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PROJECT INITIATION

Note distribution statement requirements

Date: April 1, 1974

Project Title: "UHF Band Radiofrequency Radiation for Cardiac Pacemaker EMI Studies"

Project No.: A-1614

Project Director: Mr. J. C. Toler

Sponsor: USAF Aerospace Medical Division; Brooks AFB, Texas

Effective March 1, 1974 Estimated to run until June 30, 1974 (R&D)

Type Agreement: Contract No. F41609-74-C-0021 Amount: $ 7,552.00

Reports Required: Monthly Funds Status Reports; Final Technical Report.

Sponsor Contact Person (s):

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A-73

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Engineering Experiment Station

PROJECT TERMINATION

Date October 4, 1974

PROJECT TITLE: UHF Band Radiofrequency Radiation for Cardiac Pacemakers EMI Studies

PROJECT NO: A-1614

PROJECT DIRECTOR: Mr. J. C. Toler

SPONSOR: USAF Aerospace Medical Division; Brooks AFB, Texas

TERMINATION EFFECTIVE: 8-21-74 (Final Report distribution)

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ENGINEERING EXPERIMENT STATION
GEORGIA INSTITUTE OF TECHNOLOGY • ATLANTA, GEORGIA 30332

16 April 1974

USAF School of Aerospace Medicine (AFSC)
Attn: TOP
Brooks AFB, Texas 78235

Subject: Monthly Funding Report for Period 3-1-74 to 3-31-74, Contract No. F41609-74-C-0021, "UHF Band Radio-frequency Radiation for Cardiac Pacemaker EMI Studies".

Dear Sir:

This project was initiated on 1 March 1974, and during the following 30 day period, performance evaluations were conducted on 72 different pacemakers exposed to two high power electromagnetic environments. These environments were at frequencies of 450 MHz and 3.1 GHz. The performance evaluations consisted of increasing the exposure environment intensity while monitoring the pacemaker's stimulation pulse for changes in rate, period, and waveform shape.

The following is a summary of the current funding status of the project:

a)	Costs incurred during reporting period	$4,387.60
b)	Costs incurred to date	4,387.60
c)	Costs billed to date	4,387.60
d)	Estimated expenditures to end of fiscal year	7,552.00
e)	Estimated expenditures to end of contract	7,552.00

Sincerely,

[redacted]

J.C. Toler
Project Director

Approved:

[redacted]

D.W. Robertson, Chief
Communications Division

JCT:wc

File : A-1614

ENGINEERING EXPERIMENT STATION

GEORGIA INSTITUTE OF TECHNOLOGY • ATLANTA, GEORGIA 30332

27 August 1974

USAF School of Aerospace Medicine (AFSC)
Attn: TOP
Brooks AFB, Texas 78235

Subject: Monthly Funding Report for Period 4-1-74 to 4-30-74, Contract No. F41609-74-C-0021, "UHF Band Radio-frequency Radiation for Cardiac Pacemaker EMI Studies".

Dear Sir:

This project was initiated on 1 March 1974, and during the following 30 day period, performance evaluations were conducted on 72 different pacemakers exposed to two high power electromagnetic environments. These environments were at frequencies of 450 MHz and 3.1 GHz. The performance evaluations consisted of increasing the exposure environment intensity while monitoring the pacemaker's stimulation pulse for changes in rate, period, and waveform shape. During this reporting period, efforts have been directed to data reduction and analysis.

The following is a summary of the current funding status of the project:

a)	Costs incurred during reporting period	$1681.85
b)	Costs incurred to date	6069.45
c)	Costs billed to date	6069.45
d)	Estimated expenditures to end of fiscal year	7552.00
e)	Estimated expenditures to end of contract	7552.00

Sincerely,

[redacted]

J. C. Toler
Project Director

Approved:

[redacted]

D. W. Robertson, Chief
Communications Division

JCT:swg

ENGINEERING EXPERIMENT STATION
GEORGIA INSTITUTE OF TECHNOLOGY • ATLANTA, GEORGIA 30332

27 August 1974

USAF School of Aerospace Medicine (AFSC)
Attn: TOP
Brooks AFB, Texas 78235

Subject: Monthly Funding Report for Period 5-1-74 to 5-31-74, Contract No. F41609-74-C-0021, "UHF Band Radio-frequency Radiation for Cardiac Pacemaker EMI Studies".

Dear Sir:

This project was initiated on 1 March 1974, and during the following 30 day period, performance evaluations were conducted on 72 different pacemakers exposed to two high power electromagnetic environments. These environments were at frequencies of 450 MHz and 3.1 GHz. The performance evaluations consisted of increasing the exposure environment intensity while monitoring the pacemaker's stimulation pulse for changes in rate, period, and waveform shape. During this reporting period, efforts were directed to preparation of the final report.

The following is a summary of the current funding status of the project:

a)	Costs incurred during reporting period	$2248.97
b)	Costs incurred to date	8318.42
c)	Costs billed to date	7552.00
d)	Estimated expenditures to end of fiscal year	7552.00
e)	Estimated expenditures to end of contract	7552.00

Sincerely,

[redacted]

J. C. Toler
Project Director

Approved:

[redacted]

D. W. Robertson, Chief
Communications Division

JCT:swg

Classification

Budget Bureau No.: 22-R0180

1. CONTRACT NUMBER	3. CONTRACT FUNDING FOR FOR FY	5. PREVIOUS REPORT DATE	7. CONTRACTOR (NAME, ADDRESS & ZIP CODE)	9. INITIAL CONTRACT PRICE:
F41609-74-C-0021 2/25/74		None	Ga.Tech.Res. Inst. Ga.Inst. of Tech. Atlanta, Ga. 30332	TARGET 7,552.00 CEILING 7,552.00
2. CONTRACT TYPE	**4. APPROPRIATION**	**6. CURRENT REPORT DATE**	**8. PROGRAM**	**ADJUSTED CONTRACT PRICE**
CR		6/30/74	"UHF Band Radio - frequency Radiation for Cardiac Pacemaker EMI Studies	TARGET 7,552.00 CEILING 7,552.00

11. FUNDING INFORMATION

LINE ITEM/WBS ELEMENT	APPROPRIATION IDENTIFICATION	FUNDING AUTHORIZED TO DATE	ACCRUED EXPENDITURES PLUS UNLIQUIDATED COMMITMENTS TOTAL	CONTRACT WORK AUTHORIZED				FORECAST			TOTAL REQUIREMENTS	FUNDS CARRY-OVER	NET FUNDS REQUIRED
				Definitized	Est. Over/ Under Target Cost	Not Definitized	Subtotal	Not Yet Authorized	All Other Work	Subtotal			
a.	b.	c.	d.	e.	f.	g.	h.	i.	j.	k.	l.	m.	n.
Contract		7,552	7,552	7,552			7,552				7,552		7,552

12.

	CONTRACT WORK AUTHORIZED (WITH FEE/PROFIT) - ACTUAL OR PROJECTED										
	ACTUAL TO DATE										At Completion
a. UNLIQUIDATED COMMITMENTS											
b. ACCRUED EXPENDITURES											
c. TOTAL (12a + 12b)											
13. FORECAST OF BILLINGS TO THE GOVERNMENT											

REMARKS:

FINAL TECHNICAL REPORT

PROJECT A-1614

UHF BAND RADIO FREQUENCY RADIATION FOR CARDIAC PACEMAKER STUDIES

June 1974

J. C. Toler and C. L. Espy

For

DEPARTMENT OF THE AIR FORCE
AEROSPACE MEDICAL DIVISION
BROOKS AIR FORCE BASE, TEXAS 78235

FOREWORD

This report was prepared by the Staff of the Communications Division of the Georgia Tech Engineering Experiment Station. The technical efforts described are in response to requirements of Contract No. F41609-74-C-0021, awarded by the Aerospace Medical Division of the Department of the Air Force. Internally, the effort is designated by Georgia Tech as Project A-1614. Technical activity was under the general supervision of Mr. D.W. Robertson, Chief of the Communications Division and Mr. J. C. Toler, Project Director. This report presents the objectives, activities and results of a four month project in which the performance characteristics of 72 different cardiac pacemakers were evaluated during exposure to two different electromagnetic environments. The environments were pulsed high powered fields at frequencies of 450 MHz and 3.1 GHz.

The authors wish to acknowledge the assistance provided during the pacemaker evaluations by the following individuals: Mr. B. M. Jenkins of Georgia Tech and Messrs J. C. Mitchell, W. D. Hurt, and T.O. Steiner of the Air Force School of Aerospace Medicine.

ABSTRACT

This report summarizes the research investigations undertaken by the Communications Division of the Georgia Tech Engineering Experiment Station under Air Force Contract No. F41609-74-C-0021. The research investigations were directed toward determining the susceptibility thresholds of cardiac pacemakers during exposure to pulsed electromagnetic environments at frequencies of 450 MHz and 3.1 GHz.

The experimentation involved evaluation of the pacemakers both mounted on an open air support and submerged in a saline solution. The saline solution was chemically formulated to simulate the pertinent electrical characteristics of the human body. The environmental exposure levels used during the pacemaker investigations were determined by using a combination of two techniques. In one technique, the power density at the desired location was calculated using a known transmitting antenna gain and power input. The other technique involved the use of a receiving antenna with known characteristics to measure the generated field before the pacemakers were positioned in their exposure location.

By monitoring the pacemaker's stimulation pulse while simultaneously varying parameters of the exposure field, susceptibility thresholds were measured. A total of 72 commercially available pacemakers representing ten manufacturers were evaluated. Some pacemakers showed no effect when subjected to the exposure fields, whereas others exhibited erratic stimulation pulses and still others provided no output pulse during exposure.

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1. INTRODUCTION

From conception until death, man is continuously buffeted by an invisible, highly complex, and constantly changing electromagnetic environment. This fact has been recognized for centuries, but it has only been within the past few decades that any significant research has been undertaken in the United States to determine possible effects of this buffeting. This situation can probably be related in time to the fact that only in the recent past has there been a general awareness of the electrical nature of many biological functions. This awareness has made possible numerous significant medical innovations. Perhaps these innovations are no where more apparent that in the development of electronic devices for both diagnostic and therapeutic purposes. In fact, these developments are now providing physicians with an unprecedented number of electronic devices produced and sold by an unknown number of manufacturers.

This rapid proliferation of medical devices has led to considerable public concern regarding the possibility of patient injury and facility-related hazards in the delivery of health care. This concern--some of which has been highly exaggerated--has been clearly evident in the case of cardiac pacemaker response to intense electromagnetic environments. News releases and articles in technical periodicals have publicized both real and imagined pacemaker electromagnetic susceptibility. In spite of some generally recognized exaggeration, however, the overall effect of this public concern has been beneficial in that it has precipitated research efforts directed to evaluating pacemaker performance during exposure to different electric and magnetic environments. These evaluations have revealed several areas within which pacemaker design features needed improvement. In many instances, design improvements have now been incorporated by pacemaker manufacturers and therefore current research efforts can be directed to evaluating their effectiveness. In other instances, new developmental or commercial pacemakers have become available and require an evaluation of their electromagnetic performance. The research efforts reported herein involved pacemakers of both types, i.e., units into which design modifications had been incorporated and new developmental units which have not previously been evaluated. The pacemakers evaluated totaled 72 in number and represented ten different manufacturers. Pulsed electromagnetic fields at frequencies of 450 MHz and 3.1 GHz were used as exposure environments. The rms field intensities of these exposure environments were 292 and 320 volts per meter, respectively.

Electromagnetic evaluations conducted on these pacemakers are described in the following sections of this report. Organizationally, the report initially presents a description of the test configurations used for the two test frequencies. Then the exposure environments and their calibration procedures are described. Next, the test procedures used and test results obtained are presented. Finally, conclusions evident from the test results are drawn.

2. TEST CONFIGURATION DESCRIPTIONS

The test configurations employed during these evaluations involved four different equipment arrangements as follows: (a) two equipment arrangements for the 450 MHz signal source, (b) one equipment arrangement for the 3.1 GHz signal source, and (c) one equipment arrangement for mounting and monitoring the pacemaker. The two different arrangements for the 450 MHz signal source were required since one configuration provided approximately 0-120 volts per meter and another provided approximately 100-300 volts per meter. Each of these configurations is described in the following paragraphs.

2.1 450 MHz Signal Source (0-120 Volts Per Meter) Description

The basic block diagram for this signal source is shown in Figure 1. As is evident from the figure, a commercially available signal generator provided the 450 MHz signal. Modulation for this signal was supplied by a pulse generator with a variable pulse duration and rate capability. The signal source frequency was measured by a counter which was an integral part of the signal generator, and pulse rate was determined by the computing counter. The pulsed output of the signal generator was coupled via coaxial cable to a broadband power amplifier and from there to appropriate monitoring and control equipments. From these equipments, the signal was routed through the shielded anechoic chamber wall and to a helical illuminating antenna. This antenna had left-hand circular polarization* and was positioned such that it was directed to the center of the pacemaker/lead arrangement. A view of the helical antenna as it was positioned during the pacemaker exposure is shown in Figure 2.

2.2 450 MHz Signal Source (100-300 Volts Per Meter) Description

This signal source is shown in block diagram form in Figure 3. With the exception of an additional amplifier and minor changes in the monitoring and control equipments, this configuration was basically identical to the one used in the lower field intensity range. The additional amplifier provided a gain of 8.5 dB at 450 MHz.

2.3 3.1 GHz Signal Source Description

The 3.1 GHz signal source, which is shown in the block diagram of Figure 4, consisted basically of a pulsed magnetron with necessary power supply and auxiliary devices. The power supply, pulsing circuit,

*See definitions for "polarization" and "right-handed polarized wave" on pages 418 and 500, respectively, of IEEE-STD-100-1972, "IEEE Standard Dictionary of Electrical and Electronics Terms", as approved on September 28, 1972.

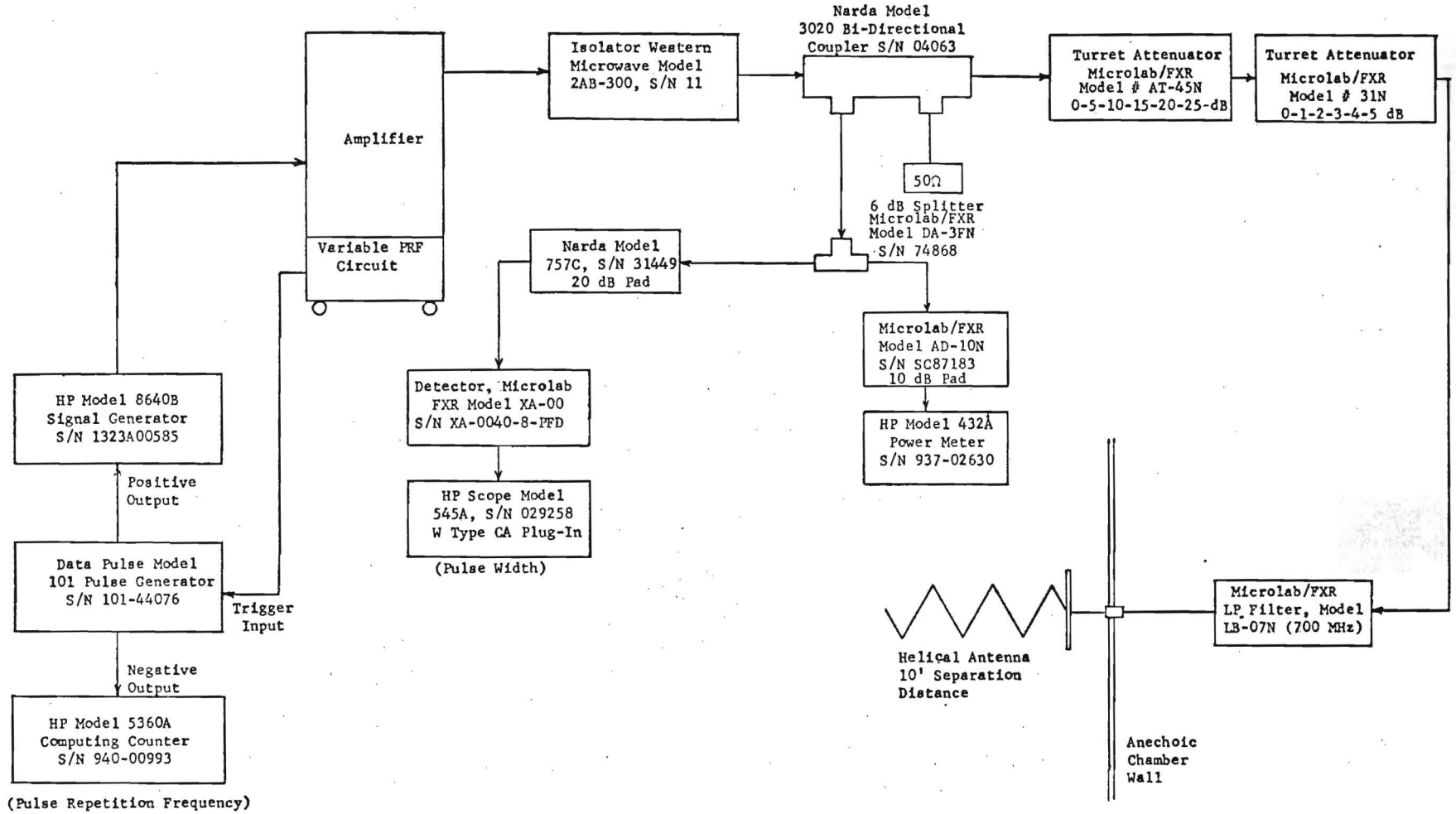

Figure 1. Block Diagram of 450 MHz Signal Source: 0-120 Volts per Meter.

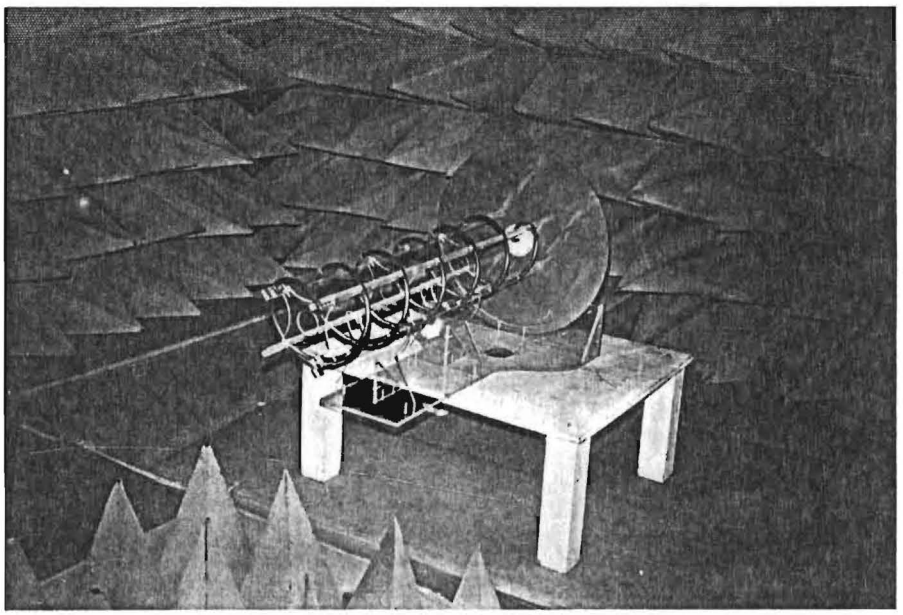

Figure 2. Helical Illuminating Antenna Used for 450 MHz Evaluations.

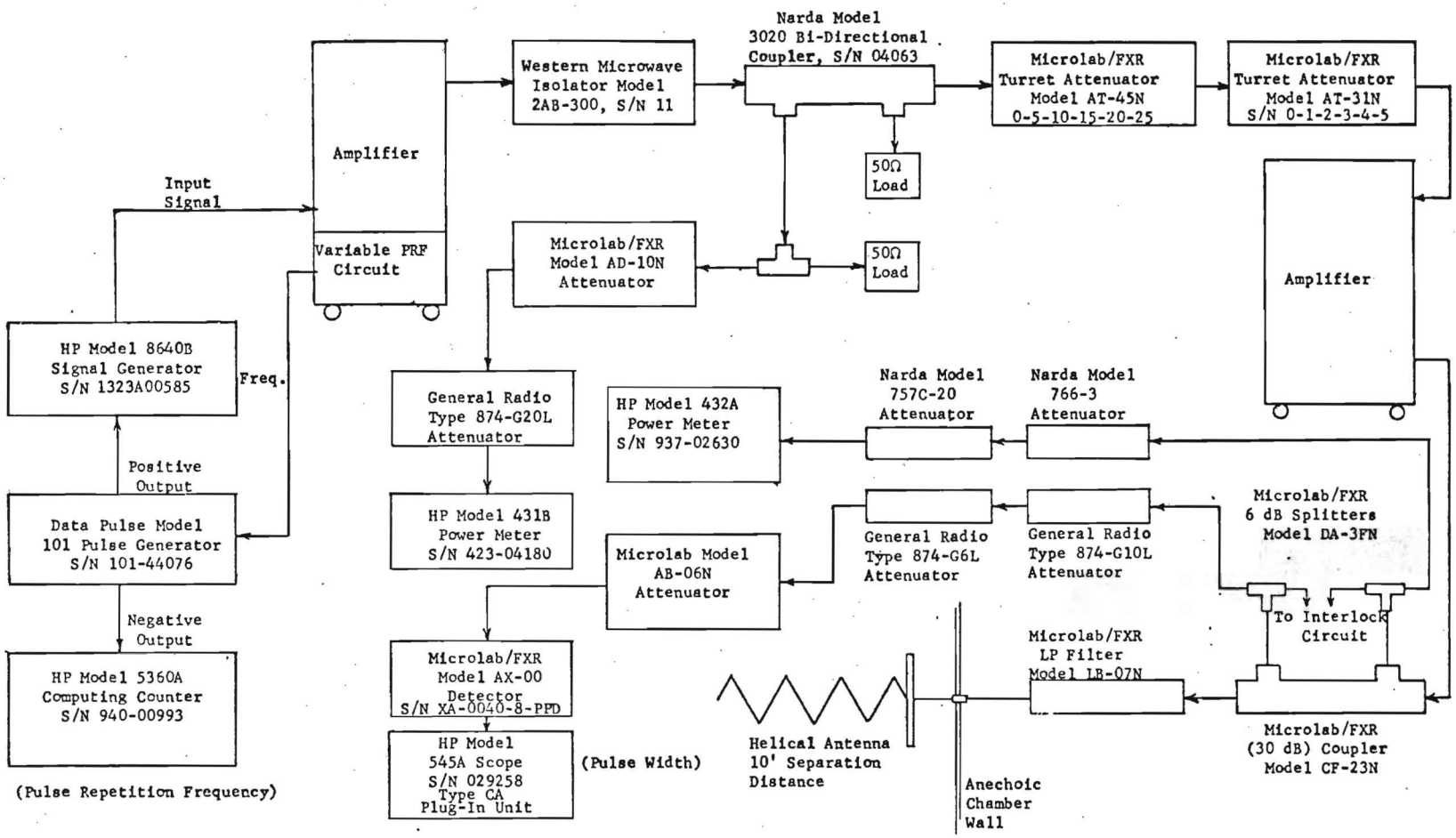

Figure 3. Block Diagram of 450 MHz Signal Source: 100-300 Volts per Meter.

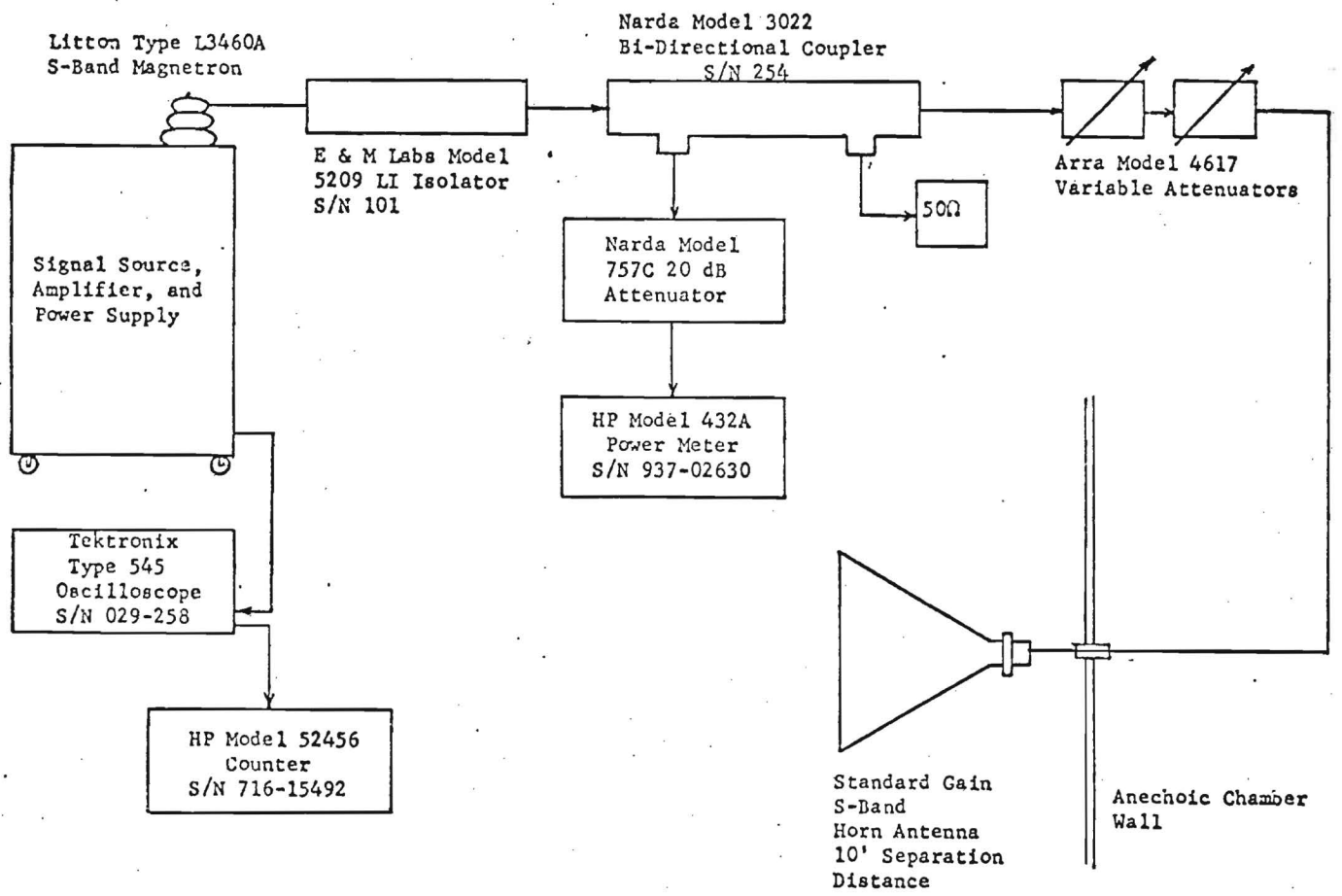

Figure 4. Block Diagram for the 3.1 GHz Signal Source.

magnetron, filament control circuit, and amplifier were mounted in two adjoining equipment racks. The magnetron output was coupled through an isolator for protection against impedance mismatches and then to a bi-directional coupler. This coupler permited measurement of both forward and reflected power during calibration and monitoring of forward power during pacemaker evaluations. The exposure environment magnitude was controlled by two high powered variable attenuators connected in series. The attenuator output was coupled through the anechoic chamber wall to a horn antenna constructed using dimensions such that a standard gain was provided over the S-band frequency range. An oscilloscope and counter connected to the signal source provided the means for monitoring pulse rate, pulse width and signal frequency. With this configuration and a ten foot separation distance, a rms field intensity of 320 volts per meter was provided at the test specimen location.

2.4 Pacemaker Mounting and Monitoring Configuration

The mounting configuration used during these evaluations was provided by the Air Force School of Aerospace Medicine (AFSAM) and is shown in block diagram form in Figure 5. The saline solution container was a plastic phantom (hereafter referred to as the SAM Phantom) with dimensions of 30 X 30 X 20 centimeters into which a Plexiglas® stand was positioned. This stand provided vertical supports for a flat sheet of Plexiglas®. It was on this sheet that the pacemakers were individually mounted during electromagnetic performance evaluations. The pacemaker leads were attached to the Plexiglas® sheet in a reversed "S" position. Both pacemaker and leads were held on the Plexiglas® sheet by rubber bands. The pacemaker leads were connected to a light emitting diode and resistive load arrangement positioned above the saline solution level. Light emissions from the diode corresponding to each pacemaker stimulation pulse were routed external to the anechoic chamber by a fiber optic light pipe. Outside the chamber, the light pipe was terminated in a light sensitive resistor across which a voltage was applied. Voltage variations caused by the stimulation pulses were amplified and routed to a computing counter and recorder. A program stored in the counter permitted either pulse period or rate to be visually displayed for observation during the field exposures. On one channel of the recorder, the stimulation pulses were recorded. The other recorder channel was connected to a monitoring antenna mounted above the pacemaker in the anechoic chamber. The detected output of this antenna provided a noncalibrated indication of changes in the exposure field magnitude.

A view of the SAM phantom saline solution container, Plexiglas® pacemaker support, monitoring antenna, and fiber optic light pipe is shown in Figure 6.

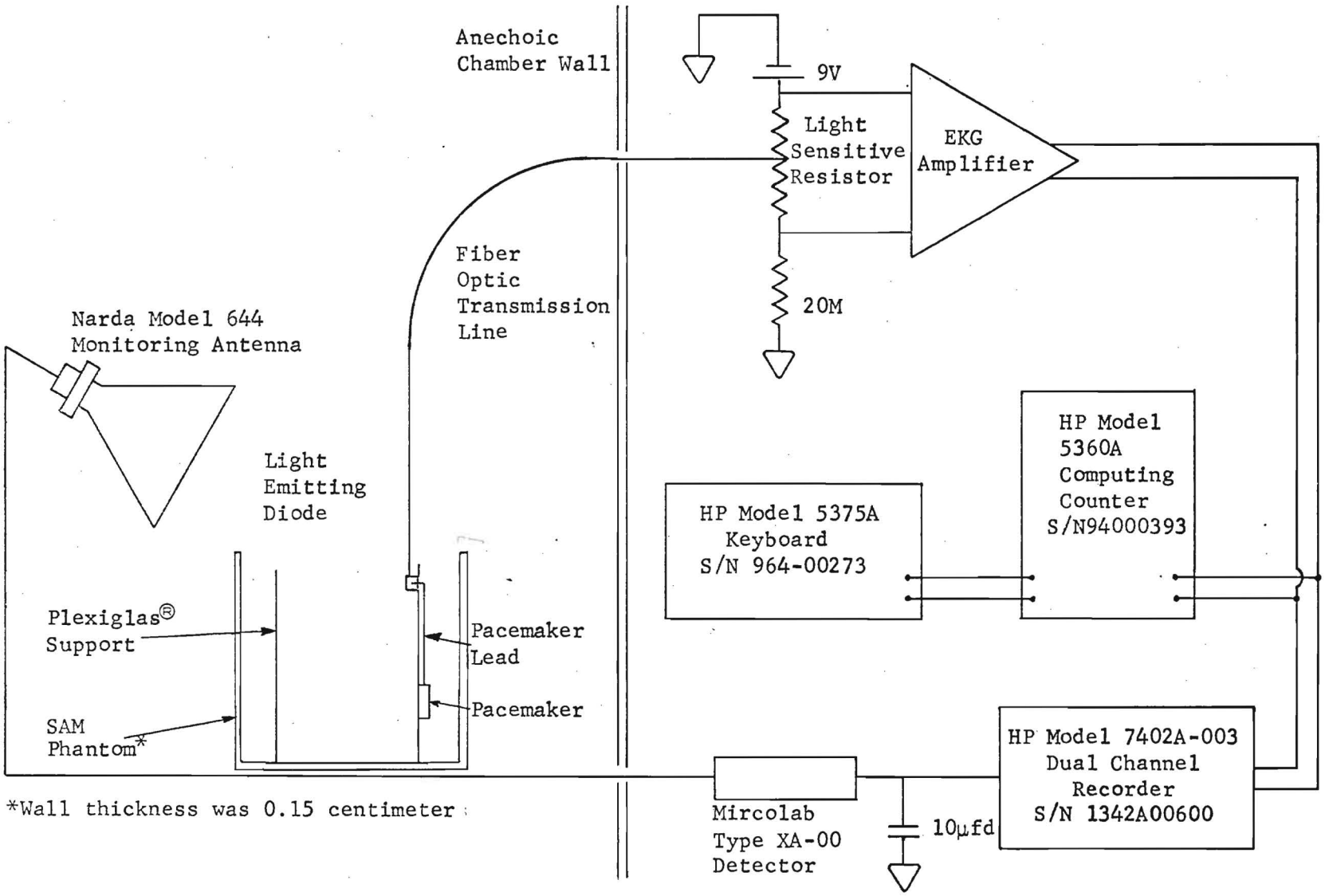

Figure 5. Block Diagram of Pacemaker Mounting and Monitoring Configuration.

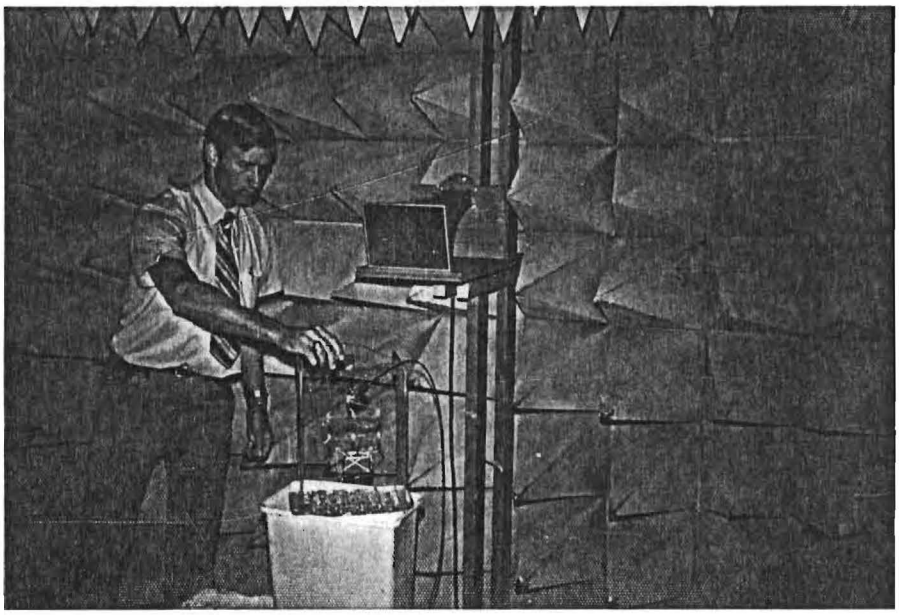

Figure 6. Configuration for Pacemaker Mounting and Monitoring.

3. EXPOSURE ENVIRONMENT DESCRIPTION

3.1 Environment Characteristics

The exposure environments at both test frequencies were pulse modulated electromagnetic fields with variable rates and widths. The range of pulse rate and width variation at the 450 MHz frequency was 2 to 50 pulses per second and 1.0 to 1000 microseconds, respectively. At the 3.1 GHz frequency, this range was 7 to 400 pulses per second and 10 to 120 microseconds. The magnitude of both environments at the pacemaker location could be varied from zero up to the maximum level by appropriate attenuators within the basic signal sources.

3.2 Environment Determination

The difficulties inherent in accurately determining exposure fields at a test specimen location are well known [1,2,3]. Two different techniques are generally available for such field determinations, and either one or both of these techniques may be used during electromagnetic radiation exposure investigations. In one technique, the power density at the desired location is calculated using a known transmitting antenna gain and power input. The other technique involves use of a receiving antenna with known characteristics to measure the generated field before the test specimen is positioned in its exposure location. Regardless of which technique is used, the accuracy of the results obtained is dependent on the accuracy with which the antenna characteristics are known, the accuracy of the instruments used to measure either transmitted or received power, and the accuracy of the various ancillary components and cables in the measurement configurations. Experience indicates that an accuracy of $\pm$ 1 dB is a realistic goal for most laboratory measurements. More accurate measurements can be made, but they would involve significantly more time and cost.

The environmental exposure levels were determined using a combination of the two techniques mentioned in the above paragraph. A description of the procedures utilized to determine the exposure field at the pacemaker location is presented in the following paragraphs.

3.2.1 Calculation Method

This method consisted of a three step process as follows: (a) measurement of power losses in the signal system, (b) measurement of forward and reflected power levels between the amplifier output and the antenna, and (c) utilization of these power losses and levels to calculate the field intensity at the pacemaker exposure position.

Measurement of the system losses was accomplished via a substitution approach in which a signal source was initially connected to a power meter by coax cable. The signal source output and power meter input were adjusted to yield an easily identified position on the power meter scale. Without changing the signal source output, the coax cable was disconnected at the power meter and a portion of the signal system was added to the setup. The cables were then reconnected, and the resulting decrease in power meter scale indication represented the loss in the inserted portion of the signal system.

The forward and reflected power levels were measured by connection of power meters to the signal ports on a bi-directional coupler positioned at the output of the final amplifier. The levels measured at these ports were modified by the appropriate signal losses such that their difference revealed the power transmitted by the antenna. It is noted that this transmitted power was the average value of the root-mean-square (rms) current across a 50 ohm impedance because the power meters responded to heat deposition in thermistor mounts.

The average value of transmitted power was then modified by the duty factor to yield the peak value of rms power during the pulse. This peak value of rms power was used in the following equation to determine the power density at the pacemaker location:

$$P_D = \frac{P_t \, G_o}{4\pi R^2} , \qquad (1)$$

where

P_D = power density in watts per square meter,

P_t = peak value of transmitted rms power in watts,

G_o = gain of illuminating antenna, and

R = distance in meters between the transmitting portion of the antenna and the pacemaker.

The value provided by this calculation was the pacemaker location power density resulting from the rms current in the signal pulse. This power density was then converted to units of field intensity using the equation

$$E = \left[P_D \, Z \right]^{\frac{1}{2}} , \qquad (2)$$

where

E = field intensity in rms volts per meters,

P_D = power density in watts per square meter, and

Z = intrinsic impedance of free space in ohms.

It is noted that, when a circularly polarized transmitting antenna is used, this level of rms volts per meter is identical to peak volts per meter. For linearly polarized transmitting antennas, the field intensity remains in units of rms volts per meter during the pulse.

3.2.2 Measurement Method

The second method for determining the exposure field consisted of measuring the actual field at the position where the pacemakers were to be located. For the 450 MHz frequency, a standard gain dipole (Scientific-Atlanta Model 15340 Dipole) with the elements and balun properly tuned was used as the probe antenna. Since the illuminating antenna was circularly polarized, the measured vertical and horizontal power levels were added together to yield the total power. At the 3.1 GHz frequency, a standard gain horn (Narda Model 644) was used as the probe antenna and the illuminating antenna was linearly polarized. The measured power levels at both frequencies were expressed in density units for the probe antenna apertures and then compared to the calculated power density.

During these measurements and the subsequent tests, caution was exercised to assure that the separation distance R was greater than the value $2D^2/\lambda$, where D is the width of the largest aperture. The expression $2D^2/\lambda$ is often referred to as the far field criteria and corresponds to the distance at which the phase variation across the illumination aperture is 22.5 degrees or less. When the phase variation meets this criteria, any error in field measurement is generally not detectable using standard laboratory instruments.

The combination calculation/measurement approach described above was used to determine values of field intensity during pacemaker exposure evaluations; however, the resulting field intensity levels do not account for inaccuracies that can exist because of equipment tolerances. Efforts were therefore undertaken to determine these tolerances and their worst case effect on individual field intensity values. The results of these efforts provided a "confidence factor" for the data later recorded as pacemaker susceptibility thresholds.

The basic measurement instrument used in field intensity determinations was the Hewlett-Packard Model 432A Power Meter with a specified accuracy of $\pm$ 1 percent. This accuracy was checked to within $\pm$ 2 percent by the Equipment Calibration Laboratory of the Systems and Techniques Department by comparison with available secondary standards. A total of

six power meter readings were made in determining losses in the signal system. Each reading was made with an accuracy within $\pm$ 2 percent. Additionally, the determination of field intensity at the pacemaker location required the measurement of forward and reverse power. Therefore, each field intensity value was based on eight power meter readings.

Two other measured quantities also influenced the field intensity values and therefore had to be included in considerations of equipment accuracy. These quantities were the gain of the illuminating antennas and the separation distance between this antenna and the pacemaker being tested. The antenna gain for the 450 MHz helix was determined by the procedure presented in paragraph 15.6,page 453, of the text Antennas, J.D. Kraus, McGraw-Hill, New York, 1950. Characteristics of the standard gain horn were accepted as published by Narda for the 3.1 GHz test frequency. Distance measurements were made with a conventional steel tape. No precise accuracy values are available for either the gain or distance measurements; however, professional judgement indicates that, as a maximum, they are within $\pm$ 10 and $\pm$ 2 percent, respectively.

If the maximum possible errors are assumed to all exist simultaneously, then the maximum probable field error can be determined from the expression

$$\epsilon\% \Big|_{max} = \epsilon_p + 2\epsilon_d + \epsilon_g \qquad (3)$$

where

ϵ_p = maximum percentage error in reading the meters,

ϵ_d = maximum percentage error in measuring distance, and

ϵ_g = maximum percentage error in gain measurement.

The resulting maximum probable error is then computed to be 16 percent.

4. TEST PROCEDURES AND RESULTS

4.1 Special Purpose Tests

The initial investigations under this program involved conducting several different special purpose tests aimed at defining parameters and conditions for use during later pacemaker evaluations. These special purpose tests are described first, followed by a description of the individual pacemaker evaluations.

4.1.1 Measurement of Signal Loss in Tank Materials

Evaluations conducted approximately two years ago to determine pacemaker susceptibility thresholds in a saline solution used tanks constructed of Plexiglas® material. This material was later shown to introduce reasonably significant attenuation and/or reflection losses at test frequencies above approximately 1 GHz. Consequently, tanks constructed of other plastics, including Ethafoam®, came to be commonly used during saline solution evaluations. This special purpose test was conducted for the purpose of comparing the electromagnetic wave transmission characteristics of tank materials as a function of frequency.

Tank materials used during these tests were sheets approximately three foot square of (1) 0.25 inch thick Plexiglas®, (2) 0.375 inch thick Plexiglas®, and (3) 2 inch thick Ethafoam® with a coating of waterproofing epoxy. The test configuration included transmitting and receiving antennas positioned ten feet apart in a shielded anechoic chamber. The transmitting antenna was connected to a high powered signal source and the receiving antenna output was routed to a power meter. For a given adjustment of the signal source, a conveniently read reference level was established on the power meter. Without changing either the signal source or power meter, the different tank materials were individually positioned in front of and one foot away from the receiving antenna. The power meter reading was noted and recorded for each of the tank materials and the resulting data are shown in Table I. As the data indicates, the Ethafoam® material resulted in no measurable signal loss at either of the test frequencies. The Plexiglas® material, however, did provide a loss, and this loss increased as the material thickness increased. The following conclusions were drawn from these measurements:

(a) For any evaluations which seek to relate pacemaker susceptibility in open air to that in a saline solution, Plexiglas® material should not be used to contain the saline solution if the test frequency is above approximately 1.0 GHz.

(b) As the Plexiglas® material was increased in thickness by 1.5, the signal loss at 3.1 GHz increased by 0.8 dB, a factor of 1.2 in power. This indicates that signal loss is significantly influenced by material attenuation as well as reflection.

TABLE I

ATTENUATION/REFLECTION CHARACTERISTICS OF DIFFERENT TANK MATERIALS

Material	Test Frequency	Reading Change
Ethafoam® without epoxy coating	430 MHz	0 dB
	3.1 GHz	0 dB
Ethafoam® with epoxy coating	430 MHz	0 dB
	3.1 GHz	0 dB
0.25 inch Plexiglas®	430 MHz	0 dB
	3.1 GHz	0.6 dB
0.375 inch Plexiglas®	430 MHz	0 dB
	3.1 GHz	1.4 dB

An additional signal loss measurement was made at 3.1 GHz using the SAM phantom. The measurement procedure described above was used with the exception that a small S-band antenna positioned on a Plexiglas® stand provided the receiving antenna. The reference level was established with this antenna and stand located outside the phantom. Signal loss was then determined by noting the power meter level after the antenna and stand were relocated inside the phantom. These measurements indicated that the SAM phantom offered no measurable attenuation at 3.1 GHz.

4.1.2 Measurement of Signal Loss in Saline Solution

From pacemaker electromagnetic performance evaluations [4,5] conducted approximately two years ago, data defining two separate but related conditions have been recognized as needed. These data would provide (1) a factor modifying susceptibility thresholds obtained in an open air medium to account for the shielding effect of body fluid and tissue, and (2) an attenuation versus depth-of-implant curve for 0.03 Molar saline solution. Measurement efforts to obtain these data have been hampered by the fact that test antenna characteristics in open air differ considerably from those in a saline solution. To circumvent this difficulty, special purpose tests that provide relative data independent of antenna characteristics were undertaken. These tests were aimed at defining an attenuation versus depth-of-implant curve for the 0.03 Molar saline solution at 3.1 GHz.

The test configuration consisted of a circularly polarized planar log spiral receiving antenna mounted on a Plexiglas® support as shown in

Figure 7. The Plexiglas® support was then positioned in a container of saline solution. This antenna was connected via coaxial cable through the shielded anechoic chamber wall to a power meter. A very thin and highly flexible plastic bag was positioned around the antenna to assure that no saline solution entered the coaxial connection to the cable. This arrangement of antenna and saline solution was illuminated by a source antenna connected by coaxial cable to a high power signal source external to the chamber. An electromagnetic field with a pulse width of 120 microseconds and a pulse rate of 400 pulses per second provided the exposure environment. Without changing the exposure field, the receiving antenna position was varied in discrete steps to provide saline solution depths from 0.25 to 3.0 centimeters between the antenna face and the inner wall of the tank. At each discrete step, the level indicated on the power meter external to the chamber was noted and recorded. The difference in recorded levels as a function of antenna position provided a relative measure of the attenuation of a 0.03 Molar saline solution. These levels are plotted in Figure 8 and indicate that each centimeter of saline solution attenuates the exposure field by approximately 4.5 dB per centimeter of saline solution. This corresponds to a change in power ratio of approximately 3 for each centimeter of saline solution at 3.1 GHz.

It should be noted that this factor can not be used to modify pacemaker susceptibility data obtained in open air to account for the shielding effects of body tissue and fluid. This is because characteristics of the probe antenna can differ appreciably when mounted in open air and saline solution mediums. Consequently, data obtained in the two mediums are not directly comparable even when the same probe antenna is used in each medium.

4.1.3 Comparison of Susceptibility Thresholds For Various Measurement Configurations

Efforts to compare pacemaker susceptibility data obtained at different locations and points in time have been hindered by the lack of standardized procedures and configurations for use during electromagnetic evaluations. This situation continues to exist in spite of the voluminous amount of data showing that the procedures and configurations can drastically effect the measured threshold. In order to define, at least on a relative basis, the effect of procedures and configurations used by AFSAM, a limited series of special tests were conducted. These tests were primarily concerned with data effects introduced by the saline solution container, the technique used for monitoring pacemaker stimulation pulse, and endocardial versus epicardial pacemaker leads.

The basic AFSAM test configuration consisted of a SAM phantom saline solution container into which was positioned a Plexiglas® pacemaker support. The SAM phantom and pacemaker support are shown in Figures 9 and 10, respectively. The pacemaker was mounted on the Plexiglas® support via rubber bands and the vertical sides of the support were grooved to permit easy removal and/or repositioning of the pacemaker support. The lead for

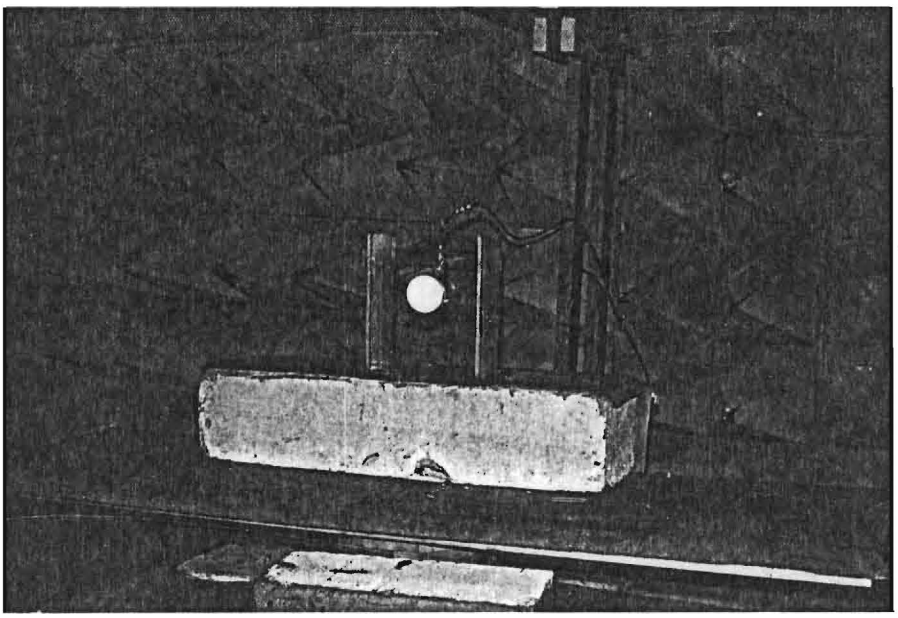

Figure 7. Receiving Antenna and Support Used in Determining Signal Loss in Saline Solution.

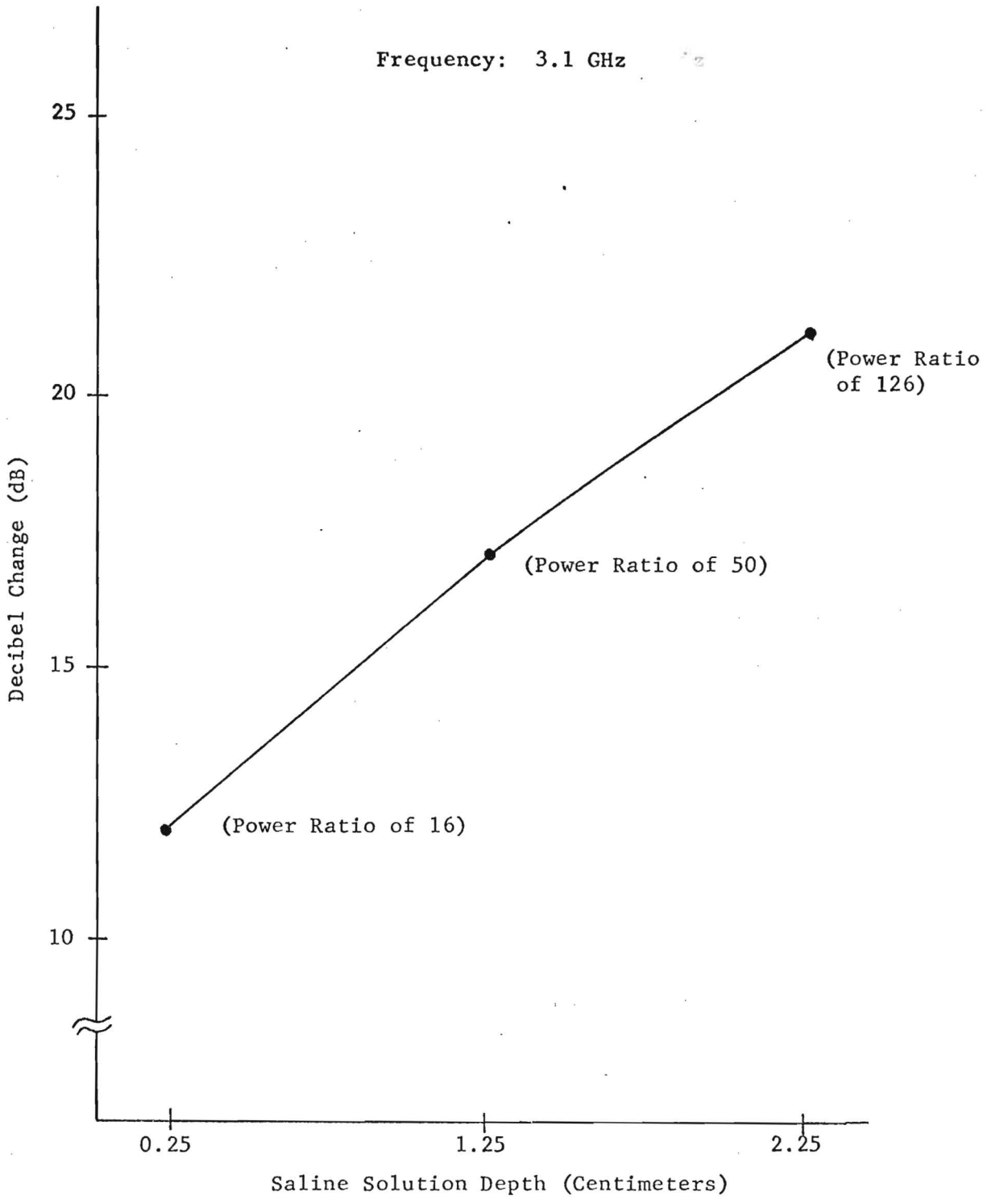

Figure 8. Relative Signal Attenuation in a 0.03 Molar Saline Solution.

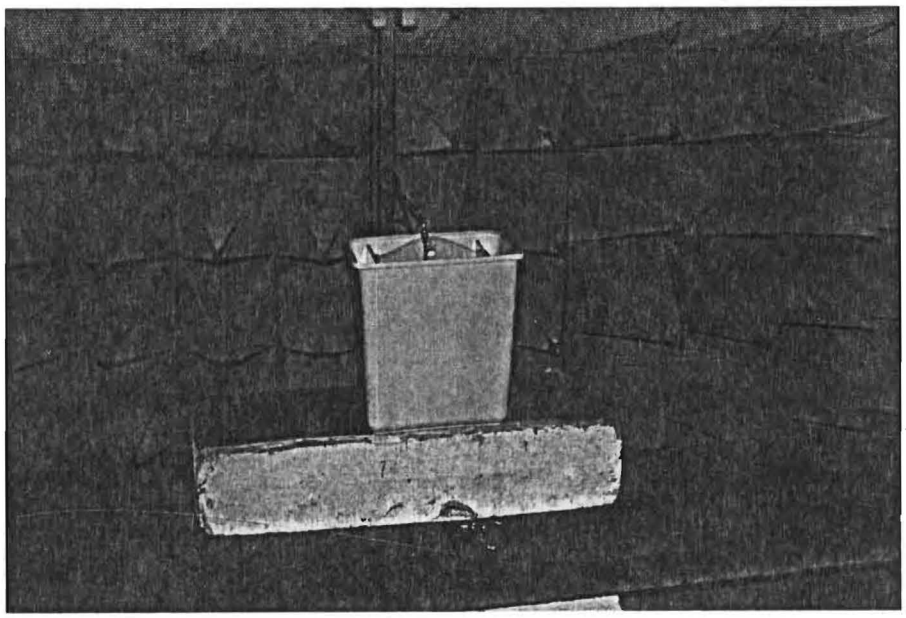

Figure 9. SAM Phantom Container for Saline Solution.

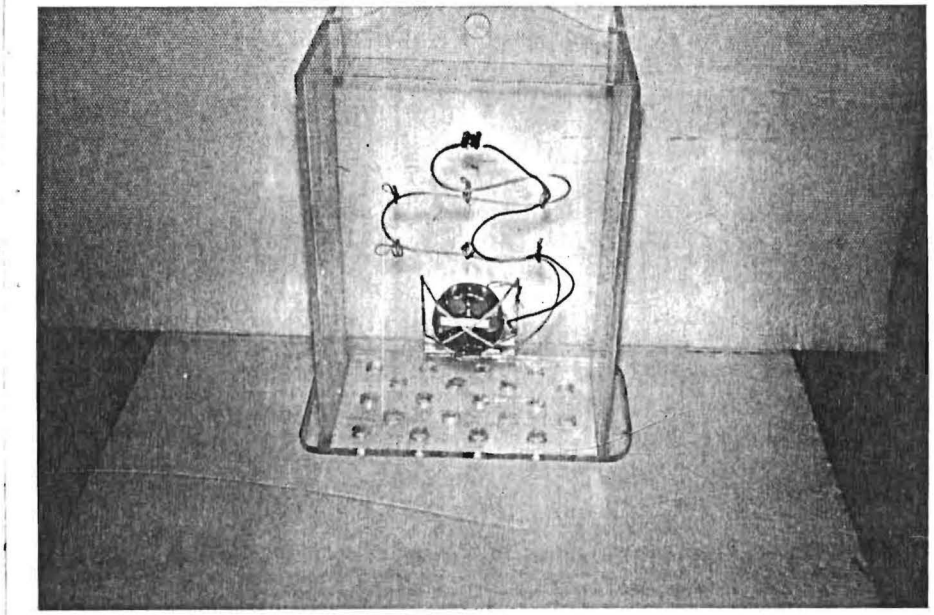

Figure 10. Plexiglas® Support for Pacemaker.

unipolar pacemakers was routed as shown in Figure 10 to an audio jack on the Plexiglas® support. Bipolar pacemaker leads were routed as shown in Figure 11. A mating audio connector was plugged into the jack and was attached to a small plastic box containing a resistive load arrangement for the pacemaker output and a light emitting diode. The resistors provided a load of approximately 500 ohms for the pacemaker while the diode provided a light emission with each pacemaker stimulation. This light emission was routed external to the anechoic chamber via a fiber optic transmission line, or light pipe. The light pipe and small plastic box are shown plugged into the audio jack in Figure 12. Because of the nature of its electrical connection, the audio jack, distal end of the pacemaker lead, plastic box, and light pipe had to be maintained out of the saline solution during all evaluations.

The basic test configuration used during previous pacemaker susceptibility evaluations at Georgia Tech consisted of an Ethafoam® saline solution container and a plywood pacemaker support. The plywood support was coated with a clear epoxy to prevent absorption of the saline solution. Rubber bands were used to mount the pacemaker to the plywood support. Dimensions of the Ethafoam® container were approximately 100 x 15 x 20 centimeters. Bronze screen electrodes positioned in either end of the container were used to monitor the pacemaker's stimulation pulse. Consequently, no electrical connection was made to the pacemaker lead and the lead was completely submerged during susceptibility evaluations. This tank, with a pacemaker submerged in the saline solution, and the screen monitoring electrodes is shown in Figure 13.

The limited tests to compare results from the two different measurement configurations were conducted at a frequency of 450 MHz. The pulse rate and width of the exposure field were 2 pulses per second and 1.0 millisecond, respectively. The pacemaker used during each test was a Medtronic Model 5944, Serial Number 3G20824. All tests were conducted in a saline solution with a 0.03 Molar concentration. The epicardial lead was a Medtronic Model 6914, Serial Number 00842U2, while the endocardial lead was a Medtronic Model 5818, Serial Number 13154G1. Results of the tests are presented in Table II.

These test results were obtained over an extremely limited number of tests, and consequently, absolute conclusions were not drawn. However, trends indicated by the data are as follows:

(a) The pacemaker was consistently more susceptible during each test in which the epicardial lead was used.

(b) The pacemaker was consistently more susceptible in the SAM phantom than in the Ethafoam® container.

(c) The GIT screen electrodes generally yielded susceptibility thresholds lower than those measured with the AFSAM light emitting diode.

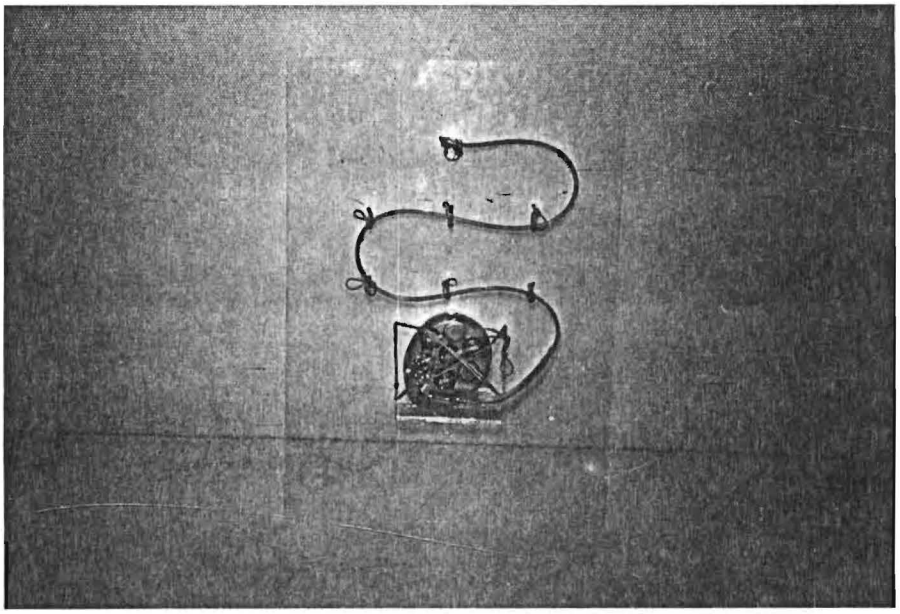

Figure 11. Routing Arrangement for Bipolar Pacemaker Leads.

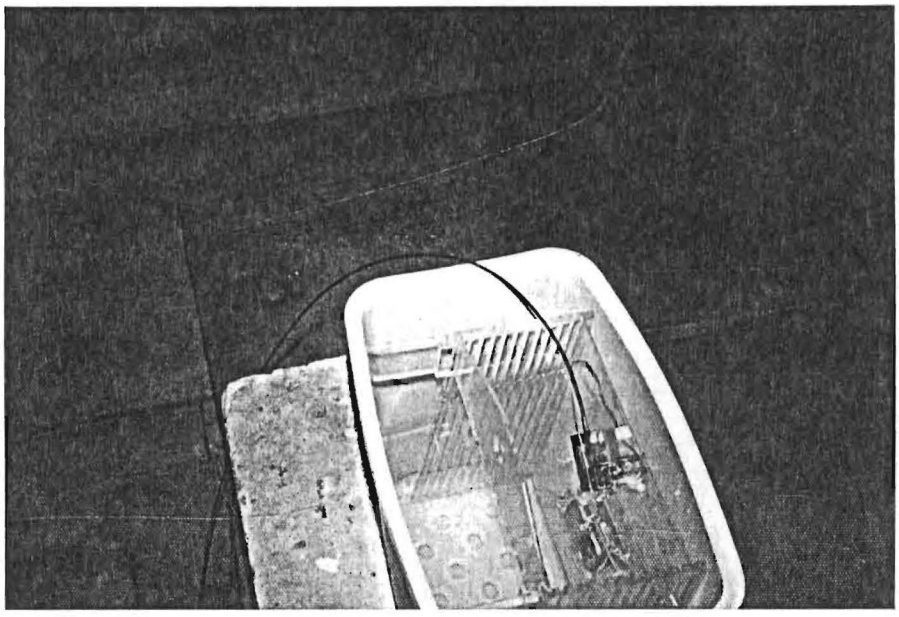

Figure 12. AFSAM Instrumentation for Monitoring Pacemaker Stimulation Pulse.

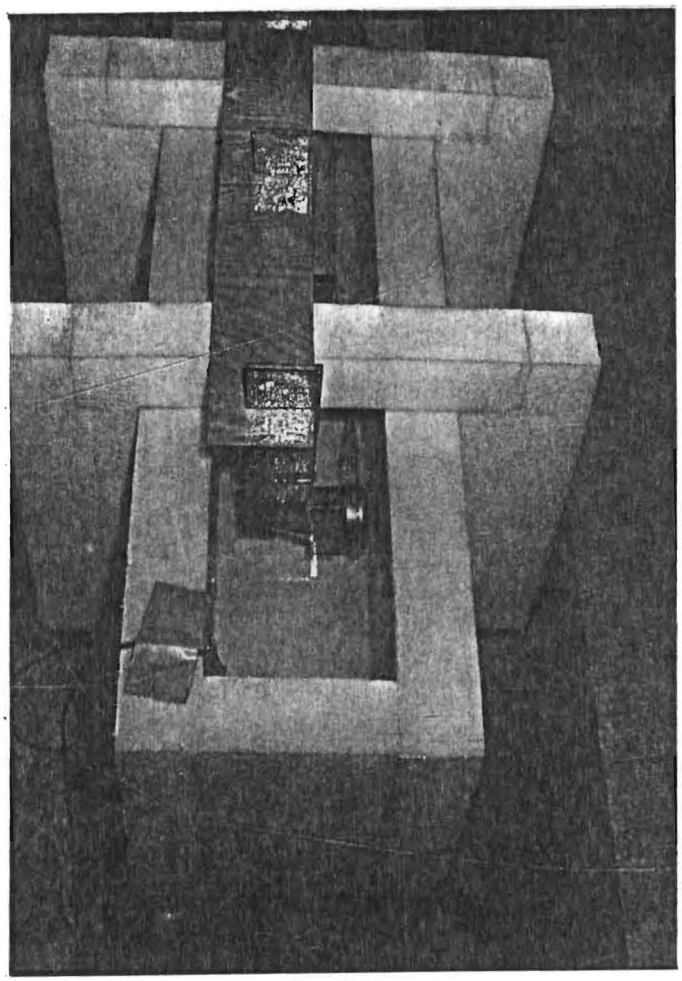

Figure 13. GIT Instrumentation for Monitoring Pacemaker Stimulation Pulse.

TABLE II

COMPARISON OF SUSCEPTIBILITY THRESHOLDS FOR VARIOUS MEASUREMENT CONFIGURATIONS

Saline Solution Container	Pacemaker Lead Type	Monitoring Electrode Type	Susceptibility Threshold (V/m)	Effect
Ethafoam® Tank	Epicardial	GIT Bronze Screens	58	No Output
Ethafoam® Tank	Epicardial	AFSAM Light Emitting Diode	46	No Output
Ethafoam® Tank	Endocardial	GIT Bronze Screens	74	No Output
Ethafoam® Tank	Endocardial	AFSAM Light Emitting Diode	141	No Output
SAM Phantom	Epicardial	GIT Bronze Screens	12	No Output
SAM Phantom	Epicardial	AFSAM Light Emitting Diode	12	No Output
SAM Phantom	Endocardial	GIT Bronze Screens	58	No Output
SAM Phantom	Endocardial	AFSAM Light Emitting Diode	74	No Output

4.2 Pacemaker Susceptibility Threshold Determination

The electromagnetic performance characteristics of a sample of 72 different pacemakers were evaluated during exposure to pulsed environments at frequencies of 450 MHz and 3.1 GHz. These evaluations were conducted under test conditions as follows: (a) constant pulse width with variable pulse rates and field intensities and (b) variable pulse widths, pulse rates and field intensities. The evaluations were conducted in both open air and saline solution mediums. Each evaluation consisted of first observing and recording the pacemaker's normal pulse rate with no field exposure. Then, for a given set of exposure parameters, the field intensity was slowly increased while the monitoring instrumentation was observed for performance changes. Performance changes of particular interest were those in which the stimulation pulse either became erratic; reverted to its "noise" rate; tracked (at some multiple increment) the pulse rate of the exposure field; or was cutoff. When such changes occurred, the pulse rate, pulse width, and field strength of the exposure environment and the particular performance change were recorded. In most instances, these conditions were then re-established to assure data repeatibility. All saline solution evaluations, unless otherwise noted in the data, were conducted with the pacemaker mounted on the Plexiglas® support and positioned in the AFSAM phantom container. Leads used with the different pacemaker models are indicated in the following table.

TABLE III

DESCRIPTION OF LEADS USED WITH PACEMAKERS DURING ELECTROMAGNETIC PERFORMANCE EVALUATIONS

Pacemaker Identification		Lead Identification	
Manufacturer	Model Number	Manufacturer	Model Number
American Optical	281003	Medtronic	6914
American Optical	281013	Medtronic	6914/5818
American Optical	281143	Medtronic	6914
Biotronik	IDP-44	Biotronik	IE-60-K
Cordis Atricor	133C7	Cordis	322-620
Cordis Stanicor	143E7	Cordis	322-620
Cordis Omnicor	162C	Cordis	322-620
Cordis Omnicor	164A	Cordis	322-620
General Electric	A2072D	General Electric	A2070CC
General Electric	A2075A	General Electric	A2070CC
Medcor	3-70A	Cordis	322-620
Medtronic	5842	Medtronic	6914/5818
Medtronic	5942	Medtronic	6914/5818
Medtronic	5950	Medtronic	6914
Medtronic	5943	Medtronic	6914
Medtronic	5951	Medtronic	6914
Medtronic	5944	Medtronic	6914/5818
Medtronic	9000	Medtronic	6914/5818
Starr-Edwards	8114	Starr-Edwards	8205A-45
Starr-Edwards	8116	Starr-Edwards	8205A-45
Stimtech	3821	Cordis	322-620
Vitatron	MIP-40-RT	Vitatron	MIP-125

Except where noted in the data, a 1.0 centimeter depth of saline was maintained between the pacemaker and inner wall of the SAM phantom.

4.2.1 450 MHz Susceptibility Thresholds as a Function of Pulse Rate and Field Intensity

The performance characteristics of 42 pacemakers were determined during exposure to a 450 MHz pulsed electromagnetic environment. The pulse width was maintained at 1.2 milliseconds while the pulse rate and field intensity were varied for each pacemaker exposure. The electromagnetic evaluations were conducted in both open air and saline solution mediums. The exposure field was circularly polarized and the maximum possible intensity was 292 volts per meter. Field intensity levels measured as pacemaker susceptibility thresholds correspond to the root-mean-square (rms) value of the field during the time the pulse was present. It is noted that this is the same as the peak value for a circularly polarized field. These levels for both open air and saline solution mediums are presented below in Table IV.

TABLE IV

PACEMAKER RESPONSE TO 450 MHz PULSED ELECTROMAGNETIC FIELD WITH VARIABLE PULSE RATE

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
American Optical [2]	281003	11591	2	7	-	Erratic Output
			2	8	-	No Output
			2	-	13	Erratic Output
			2	-	15	No Output
			20	-	12	Reverted
			20	-	13	Erratic Output
			20	-	15	No Output
			40	-	10	Reverted
			40	-	107	Erratic Output
			40	-	243	No Output
American Optical [1]	281013	A2545	2	6	-	No Output
			2	206	-	Tracking
			2	-	26	No Output
			20	-	26	No Output
			40	-	26	Reverted
			40	-	206	Erratic Output
			40	-	243	No Output
American Optical [1]	281143	27322	2	292	-	No Effect
			2	-	292	No Effect
			40	-	292	No Effect

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
American Optical[1]	281143	27560	2	-	292	No Effect
			40	-	292	No Effect
American Optical[1]	281143	27312	2	-	292	No Effect
			40	-	292	No Effect
Biotronik[1]	IDP-44	61034	2	40	-	No Output
			2	-	141	No Output
			4	-	141	No Output
			10	-	141	Reverted
			20	-	141	Reverted
Biotronik[1]	IDP-44	61035	4	-	178	No Output
			10	-	178	Reverted
Biotronik[1]	IDP-44	61443	4	-	292	No Effect
			10	-	292	No Effect
Cordis Atricor[2]	133C7	2352	2	17	-	Tracking
			2	-	85	Tracking
			2	-	292	Erratic Output
			40	-	85	Tracking
			40	-	92	Tracking
Cordis Stanicor[1]	143E7	11575	2	10	-	No Output
			2	-	15	No Output
			10	-	15	No Output
			20	-	15	Reverted
			20	-	292	No Output
			40	-	15	Reverted
Cordis Omni Stanicor[2]	162C	342	2	8	-	No Output
			2	-	8	No Output
			10	-	9	No Output
			10	-	40	No Output
			10	-	51	Reverted
			10	-	92	No Effect

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Cordis Omni Stanicor[2]	162C	342	20	-	9	No Effect
			20	-	13	No Output
			20	-	292	No Effect
Cordis Omni Stanicor[2]	162C	4246	2	10	-	No Output
			2	-	15	No Output
			20	-	15	No Output
			20	-	21	No Effect
			20	-	292	No Effect
			40	-	15	Reverted
Cordis Omni Stanicor[2]	162C	5296	10	-	12	Erratic Output
			10	-	17	No Output
			10	-	51	Reverted
			20	-	12	Reverted
			40	-	12	Reverted
			40	-	51	No Effect
			40	-	292	Reverted
Cordis Omni Atricor[2]	164A	118	2	4	-	Erratic Output
			2	-	21	Tracking
			10	-	17	Erratic Output
			10	-	19	Tracking
			10	-	23	Erratic Output
			10	-	29	Reverted
			40	-	17	Reverted
Cordis Omni Atricor[2]	164A	284	2	-	13	Tracking
			10	-	13	Erratic Output
			10	-	15	Tracking
			10	-	19	Reverted
			40	-	118	No Effect
Cordis Omni Atricor[2]	164A	286	2	-	85	Tracking
			10	-	85	Tracking
			10	-	93	Erratic Output

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Cordis Omni Atricor[2]	164A	286	10	-	92	Tracking
			10	-	114	Reverted
General Electric[3]	A2072D	891930	2	8	-	Reverted
			2	12	-	No Output
			2	-	29	Erratic Output
			2	-	33	No Output
			2	-	114	Tracking
			10	-	29	Reverted
			10	-	92	Tracking
General Electric[3]	A2075A	937015	2	10	-	No Output
			2	-	51	No Output
			2	-	206	Tracking
			10	-	51	Reverted
			10	-	114	Tracking
General Electric[3]	A2075A	937147	2	-	23	No Output
			2	-	92	Tracking
			10	-	33	Reverted
			10	-	92	Tracking
General Electric[3]	A2075A	937164	2	-	36	Erratic Output
			2	-	40	No Output
			2	-	206	Tracking
			10	-	36	No Output
			10	-	40	Reverted
			10	-	92	Tracking
Medcor[2]	3-70A	2015	2	13	-	No Output
			2	-	29	Erratic Output
			2	-	33	No Output
			10	-	33	Reverted
			10	-	141	No Output
			20	-	29	Erratic Output
			20	-	33	Reverted

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medcor[2]	3-70A	3753	2	-	33	No Output
			10	-	33	Reverted
			10	-	51	Erratic Output
			10	-	114	Reverted
			10	-	141	No Output
Medcor[2]	3-70A	3754	2	-	58	No Output
			10	-	58	Reverted
			10	-	141	No Output
Medtronic[2]	5842	3M00123	2	5	-	No Output
			2	178	-	Reverted
			2	-	15	No Output
			2	-	114	Tracking
			20	-	15	No Output
			20	-	114	Tracking
			40	-	15	No Output
			40	-	114	Tracking
			50	-	15	No Output
			50	-	17	Reverted
			50	-	85	No Output
			50	-	114	Tracking
Medtronic[2]	5842	3M00154	40	-	13	No Output
			40	-	17	Reverted
			40	-	21	No Output
			40	-	141	Tracking
			50	-	13	No Output
			50	-	15	Reverted
			50	-	85	No Output
			50	-	114	Tracking
Medtronic[2]	5842	3M00158	2	-	12	No Output
			2	-	118	Tracking
			20	-	12	Reverted
			20	-	13	No Output
			40	-	13	Erratic Output
			40	-	15	No Output
			40	-	19	Erratic Output
			40	-	23	Reverted
			40	-	40	Erratic Output

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic [2]	5842	3M00158	40	-	46	Reverted
			40	-	51	No Output
			50	-	13	Erratic Output
			50	-	21	Reverted
Medtronic [2]	5942	3K04597	2	3	-	Erratic Output
			2	4	-	No Output
			2	-	12	No Output
			40	-	12	No Output
			50	-	12	Reverted
Medtronic [2]	5942	3K20660	40	-	26	No Output
			50	-	26	No Output
			50	-	29	Reverted
Medtronic [2]	5942	3K29624	40	-	51	No Output
			40	-	58	Reverted
			20	-	51	No Output
			50	-	51	Reverted
Medtronic [1]	5943	1L1282N	2	6	-	Erratic Output
			2	7	-	Reverted
			2	8	-	No Output
			2	114	-	Tracking
			2	-	23	Erratic Output
			2	-	26	No Output
			20	-	19	Erratic Output
			20	-	21	Reverted
			20	-	23	No Output
			40	-	19	Erratic Output
			40	-	21	Reverted
			40	-	292	Erratic Output
Medtronic [2]	5944	3G20824	2	6	-	No Output
			2	-	26	No Output
			20	-	19	Reverted
			40	-	19	Reverted
			40	-	207	Tracking
			10	-	19	No Output
Medtronic [2]	5944	3G20877	10	-	26	No Output
			20	-	26	Reverted

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5944	3G20881	10	-	33	No Output
			20	-	33	Reverted
Medtronic[1]	5950	3XX1022	2	292	-	No Effect
			2	-	292	No Effect
Medtronic[1]	5951	3XX2025	2	292	-	No Effect
			2	-	292	No Effect
			40	-	292	No Effect
Medtronic[1]	9000	3R00001	2	1	-	No Output
			2	-	21	Erratic Output
			2	-	23	No Output
			20	-	17	Reverted
			20	-	19	No Output
			40	-	21	Reverted
Medtronic[1]	9000	3R00003	40	-	10	Reverted
			20	-	10	No Output
Medtronic[1]	9000	3R00004	40	-	7	Reverted
			20	-	7	Reverted
			20	-	8	No Output
Pacesetter[2]	BD-101	1196KC	2	292	-	No Effect
			2	-	292	No Effect
			40	-	292	No Effect
Pacesetter[2]	BD-101	1395ND	2	-	292	No Effect
			40	-	292	No Effect
Pacesetter[2]	BD-101	1404ND	2	-	292	No Effect
			40	-	292	No Effect
Starr-Edwards[2]	8114	4399	2	33	-	No Output
			2	-	23	No Output
			10	-	29	Tracking
			10	-	46	Reverted
			20	-	26	Reverted
Starr-Edwards[2]	8116	ELX15514	2	292	-	No Effect

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Starr-Edwards[2]	8116	ELX15514	2	-	292	No Effect
			40	-	292	No Effect
Starr-Edwards[2]	8116	ELX15518	2	-	292	No Effect
			40	-	292	No Effect
Starr-Edwards[2]	8116	ELX15520	2	-	292	No Effect
			40	-	292	No Effect
Stimtech[1]	3821	H3B030	2	46	-	No Output
			2	-	107	No Output
			10	-	114	No Output
			20	-	114	Reverted
			20	-	141	Tracking
Stimtech[1]	3821	J3B015	2	-	292	No Effect
			20	-	292	No Effect
Stimtech[1]	3821	J3B016	2	-	114	No Output
			10	-	114	No Output
			10	-	141	Reverted
Stimtech[1]	3821	H3B030	10	-	114	No Output
(Retest)			20	-	114	Reverted
			40	-	114	Reverted
Stimtech[1]	3821	J3B015	10	-	243	No Output
(Retest)			20	-	292	No Output
			40	-	292	No Output
Vitatron[3]	MIP-40-RT 0505		2	40	-	No Output
			2	-	141	No Output
			10	-	141	No Output
			10	-	178	No Effect
			10	-	206	Reverted
			10	-	243	No Output
			20	-	141	Reverted
			20	-	243	No Output
			40	-	141	Reverted
			40	-	178	No Effect
			40	-	243	No Output

(Continued)

TABLE IV (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Vitratron [3]	MIP-40-RT	0507	2	-	93	No Output
			10	-	178	Reverted
			10	-	243	No Output
			40	-	114	Reverted
			40	-	243	No Output
Vitratron [3]	MIP-40-RT	5146	2	-	93	Erratic Output
			2	-	107	No Output
			10	-	107	No Output
			20	-	114	Erratic Output
			20	-	141	Reverted
			20	-	243	No Output
Vitratron [3] (Retest)	MIP-40-RT	0505	2	-	178	No Output
			10	-	178	No Output
			10	-	206	Reverted
			20	-	178	Reverted
			40	-	141	Reverted
Vitratron [3] (Retest)	MIP-40-RT	0507	2	-	85	No Output
			10	-	85	No Output
			10	-	114	Reverted
			20	-	85	Reverted
Vitratron [3] (Retest)	MIP-40-RT	5146	10	-	141	No Output
			10	-	178	Erratic Output
			10	-	206	Reverted
			10	-	292	Tracking
			20	-	178	Reverted
			20	-	292	Tracking
Medtronic [2] (Retest)	5944	3G20824	10	-	21	No Output
			20	-	21	Reverted
			20	-	292	Erratic Output
			40	-	21	Reverted
			40	-	178	Erratic Output
Medtronic [2] (Retest)	5944	3G20877	10	-	51	No Output
			20	-	51	Reverted
			40	-	51	Reverted

(Continued)

TABLE IV (Concluded)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2] (Retest)	5944	3G20881	40	-	33	Erratic Output
			20	-	36	Erratic Output
			40	-	36	Reverted
			20	-	51	Reverted
			10	-	33	No Output
Medtronic[1] (Retest)	9000	3R00001	10	-	26	No Output
			20	-	29	No Output
Medtronic[1] (Retest)	9000	3R00003	40	-	29	No Output
			10	-	10	No Output
			20	-	10	No Output
			40	-	10	Reverted
Medtronic[1] (Retest)	9000	3R00004	10	-	9	Erratic Output
			10	-	10	No Output
			20	-	10	Reverted
			20	-	13	No Output
			40	-	10	Reverted

Notes: 1. Pacemaker positioned such that label was toward antenna.
2. Pacemaker positioned such that label was away from antenna.
3. Pacemaker positioned such that ground plate was away from antenna.

4.2.2 450 MHz Susceptibility Thresholds As A Function of Pulse Rate, Pulse Width, and Field Intensity

Electromagnetic evaluations were conducted on 13 different pacemakers exposed to a 450 MHz environment in which pulse rate, pulse width, and field intensity were varied. All of these evaluations were conducted in an open air medium and a circularly polarized exposure field was used. As in the case of previously described evaluations at 450 MHz, the measured susceptibility thresholds are expressed in terms of the rms (or peak) field intensity during the time the pulse was present. These thresholds are presented below in Table V.

TABLE V

PACEMAKER RESPONSE TO A 450 MHz PULSED ELECTROMAGNETIC FIELD WITH VARIABLE PULSE RATE AND WIDTH

Pacemaker Identification			Pulse Parameters			
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	Threshold Level (V/m)	Pacemaker Response
A.O.[2]	281003	11591	1000	2	6	Reverted
			1000	2	9	No Output
			1000	50	7	Reverted
			500	2	9	No Output
			500	50	9	Reverted
			200	2	12	No Output
			200	50	19	Reverted
			100	2	17	No Output
			100	50	17	Reverted
			50	2	19	Erratic
			50	50	21	Reverted
			20	2	26	No Output
			20	50	26	Reverted
			10	2	29	Reverted
			10	2	33	No Output
			10	50	33	Reverted
			5	2	36	No Output
			5	50	36	Reverted
			2	2	51	No Output
			2	50	58	Reverted
			1	2	66	No Output
			1	50	74	Reverted
A.O.[1]	281013	A2545	1000	2	6	No Output

(Continued)

TABLE V (Continued)

Pacemaker Identification			Pulse Parameters			
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	Threshold Level (V/m)	Pacemaker Response
A.O.[1]	281013	A2545	1000	50	6	Reverted
			500	2	8	No Output
			500	50	12	Reverted
			200	2	12	Reverted
			200	50	8	Erratic Output
			100	2	15	No Output
			100	50	13	Erratic Output
			50	2	19	No Output
			50	50	19	Reverted
			20	2	23	Reverted
			20	2	26	No Output
			20	50	26	Reverted
			10	2	29	No Output
			10	50	33	Reverted
			5	2	36	No Output
			5	50	33	Reverted
			2	2	74	No Output
			2	50	74	Reverted
			1	2	107	No Output
			1	50	102	Reverted
Cordis Omni Stanicor[2]	162C	342	1000	2	6	No Output
			1000	50	6	Reverted
			500	2	8	No Output
			500	50	8	Reverted
			200	2	13	No Output
			200	50	13	Reverted
			100	2	19	No Output
			100	50	19	Reverted
			50	2	26	No Output
			50	50	26	Reverted
			20	2	40	No Output
			20	50	40	Reverted
			10	2	66	No Output
			10	50	66	Reverted
			5	2	93	No Output
			5	50	93	Reverted
			2	2	178	No Output
			2	50	178	Reverted
			1	2	243	No Output
			1	50	206	No Output

(Continued)

TABLE V (Continued)

Pacemaker Identification			Pulse Parameters		Threshold Level	Pacemaker Response
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	(V/m)	
Cordis Omni Atricor[2]	164A	118	1000	2	4	Tracking
			1000	50	4	Reverted
			500	2	5	Erratic Output
			500	50	7	Reverted
			200	2	8	Tracking
			200	50	9	Reverted
			100	2	12	Tracking
			100	50	12	Erratic Output
			50	2	17	No Output
			50	50	17	Reverted
			20	2	26	Tracking
			20	50	26	Reverted
			10	2	36	Tracking
			10	50	36	Erratic Output
			5	2	66	Reverted
			5	50	74	Reverted
			2	2	66	Reverted
			2	50	114	Reverted
			1	2	141	Reverted
			1	50	141	Reverted
General Electric[3]	A2075A	937015	1000	2	15	No Output
			500	2	19	No Output
			200	2	26	No Output
			100	2	29	Erratic Output
			100	2	33	No Output
			50	2	33	Erratic Output
			50	2	36	No Output
			20	2	36	Erratic Output
			20	2	40	No Output
			10	2	40	Erratic Output
			10	2	51	No Output
			5	2	46	Reverted
			5	50	46	No Output
Medcor[2]	3-70A	2015	1000	2	17	No Output
			1000	50	17	Reverted
			500	2	17	No Output
			500	50	17	Reverted
			200	2	21	No Output
			200	50	15	Erratic Output

(Continued)

TABLE V (Continued)

Pacemaker Identification			Pulse Parameters			
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	Threshold Level (V/m)	Pacemaker Response
Medcor[2]	3-70A	2015	100	2	26	No Output
			100	50	26	Reverted
			50	2	29	Erratic Output
			50	50	29	No Output
			20	2	40	No Output
			10	2	46	No Output
			5	2	51	Erratic Output
			5	2	58	Tracking
Medtronic[2]	5842	3M00123	1000	2	3	No Output
			100	50	3	No Output
			100	50	5	Reverted
			500	2	3	No Output
			500	50	3	No Output
			500	50	4	Reverted
			200	2	5	Erratic Output
			200	50	5	No Output
			100	2	6	No Output
			100	50	7	No Output
			50	2	9	No Output
			50	50	9	No Output
			50	50	10	Reverted
			20	2	15	No Output
			20	50	15	No Output
			10	2	21	No Output
			10	50	21	No Output
			5	2	26	Erratic Output
			5	50	26	No Output
			2	2	40	No Output
			2	50	40	No Output
			1	2	58	No Output
			1	50	58	No Output
Medtronic[2]	5942	3K04597	1000	2	2	No Output
			1000	50	2	Erratic Output
			1000	50	3	Reverted
			500	2	3	No Output
			500	50	3	No Output
			200	2	5	No Output
			200	50	5	No Output
			100	2	6	No Output

(Continued)

TABLE V (Continued)

Pacemaker Identification			Pulse Parameters		Threshold Level	Pacemaker Response
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	(V/m)	
Medtronic[2]	5942	3K04597	100	50	6	No Output
			50	2	8	No Output
			50	50	8	No Output
			20	2	13	No Output
			20	50	13	No Output
			10	2	19	No Output
			10	50	19	No Output
			5	2	23	No Output
			5	50	23	No Output
			2	2	36	No Output
			2	50	36	No Output
			1	2	46	Erratic Output
			1	50	46	Erratic Output
Medtronic[2]	5944	3G20824	1000	2	5	No Output
			1000	50	5	Reverted
			500	2	6	No Output
			500	50	6	Reverted
			200	2	9	Erratic Output
			200	50	9	Reverted
			100	2	13	No Output
			100	50	13	Reverted
			50	2	19	No Output
			50	50	19	Reverted
			20	2	23	No Output
			20	50	23	Reverted
			10	2	29	No Output
			10	50	29	Reverted
			5	2	40	No Output
			5	50	40	Reverted
			2	2	58	No Output
			2	50	51	Reverted
			1	2	74	No Output
			1	50	66	Reverted
Medtronic[1]	9000	3R00001	1000	2	1	No Output
			1000	50	1	Reverted
			500	2	1	No Output
			500	50	1	Reverted

(Continued)

TABLE V (Continued)

Pacemaker Identification			Pulse Parameters		Threshold Level	Pacemaker Response
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	(V/m)	
Medtronic[1]	9000	3R00001	200	2	1	Erratic Output
			200	50	1	Reverted
			100	2	2	Erratic Output
			100	50	2	Reverted
			50	2	3	No Output
			50	50	2	Reverted
			20	2	5	No Output
			20	50	4	Reverted
			10	2	6	No Output
			10	50	6	Reverted
			5	50	8	Reverted
			2	2	13	No Output
			2	50	12	Reverted
			1	2	19	No Output
			1	50	17	Reverted
Starr-Edwards[3]	8114	4399	1000	2	29	Reverted
			1000	50	33	Reverted
			500	2	36	Tracking
			500	50	40	Reverted
			200	2	46	Erratic Output
			200	50	46	Reverted
			100	2	58	Erratic Output
			100	2	66	Tracking
			100	50	66	Reverted
			50	2	85	Tracking
			50	50	81	Reverted
			20	2	107	Tracking
			20	50	118	Reverted
			10	2	114	Tracking
			10	50	114	Reverted
			5	2	141	Tracking
			5	50	141	Reverted
			2	2	178	Tracking
			2	50	178	Reverted
			1	2	206	Tracking
			1	50	206	Reverted
Stimtech[1]	3821	H3B030	1000	2	40	No Output
			1000	50	46	Reverted
			500	2	58	No Output

(Continued)

TABLE V (Concluded)

Pacemaker Identification			Pulse Parameters		Threshold Level	Pacemaker Response
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	(V/m)	
Stimtech[1]	3821	H3B030	500	50	58	Reverted
			200	2	85	No Output
			200	50	93	Reverted
			100	2	107	No Output
			100	50	114	Reverted
			50	2	141	No Output
			50	50	206	Reverted
			20	2	206	No Output
			20	50	206	Reverted
			10	2	243	No Output
			10	50	292	Reverted
			5	2	292	No Output
			5	50	292	No Effect
			2	2	292	No Effect
			2	50	292	Reverted
Vitatron[3]	MIP-40-RT	0505	1000	2	51	No Output
			1000	50	66	Reverted
			1000	50	292	No Output
			500	2	74	No Output
			500	50	74	Reverted
			200	2	107	No Output
			200	50	107	Reverted
			100	2	141	No Output
			100	50	141	Reverted
			50	2	178	No Output
			50	50	178	Reverted
			20	2	292	No Effect
			20	50	292	Reverted

Notes: 1. Pacemaker positioned such that label was toward antenna.
2. Pacemaker positioned such that label was away from antenna.
3. Pacemaker positioned such that ground plate was away from antenna.

4.2.3 3.1 GHz Susceptibility Thresholds As A Function of Pulse Rate and Field Intensity

Electromagnetic performance characteristics were determined during pacemaker exposure to a 3.1 GHz pulsed electromagnetic environment whose pulse width was maintained constant at 120 microseconds. Pulse rate and field intensity were varied during the evaluation. The pacemakers were mounted in both open air and saline solution mediums. In the open air medium, the pacemakers were positioned on the Plexiglas® support and in the SAM phantom saline solution container. For the saline medium, the solution was poured into the container and the evaluation was then repeated. Therefore, data differences for the two mediums were not influenced by introduction of the saline solution container or any variation in mounting arrangement. The exposure field was vertically polarized and the maxium possible intensity was 320 volts per meter. Field intensity levels measured as pacemaker susceptibility thresholds correspond to the rms value of the field during the time the pulse was present. The electromagnetic performance characteristics of the 72 pacemakers evaluated are presented as field intensity levels in Table VI.

TABLE VI

PACEMAKER RESPONSE TO 3.1 GHz PULSED ELECTROMAGNETIC FIELD WITH VARIABLE PULSE RATE

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
A.O.[2]	281003	A6124	400	88	-	Reverted
			200	77	-	Reverted
			100	77	-	Reverted
			40	88	-	Reverted
			40	102	-	Erratic Output
			20	70	-	No Output
			20	229	-	Erratic Output
			10	70	-	No Output
A.O.[2]	281003	A6995	400	141	-	Erratic Output
			400	204	-	Reverted
			200	141	-	Reverted
			100	141	-	Erratic Output
			100	204	-	Reverted
			40	128	-	Erratic Output
			40	204	-	Reverted

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
A.O.[2]	281003	A6995	20	128	-	Erratic Output
			20	229	-	No Output
			10	229	-	No Output
A.O.[2]	281003	11591	400	141	-	Erratic Output
			400	204	-	Reverted
			400	-	>320	No Effect
			200	129	-	Reverted
			100	129	-	Reverted
			100	-	>320	No Effect
			40	159	-	Erratic Output
			40	204	-	Reverted
			20	129	>320	Erratic Output
			20	141	-	No Output
			10	129	-	Erratic
			10	141	-	No Output
A.O.[1]	281013	A2202	400	52	-	Erratic Output
			400	102	-	Reverted
			200	57	-	Reverted
			100	57	-	Erratic Output
			100	102	-	Reverted
			40	47	-	Erratic Output
			20	70	-	Erratic Output
			20	77	-	No Output
			10	64	-	Erratic Output
			10	70	-	Reverted
			10	77	-	No Output
A.O.[1]	281013	A2545	400	52	-	Reverted
			400	320	-	Erratic Output
			200	43	-	Reverted
			100	52	-	Reverted
			40	64	-	Reverted
			40	302	-	No Output
			20	57	-	No Output
			20	-	320	Reverted
			10	57	-	No Output

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
A.O.[1]	281013	A2545	10	-	>320	No Effect
A.O.[1]	281143	27322	400	>320	-	No Effect
			100	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
A.O.[1]	281143	27560	400	>320	>320	No Effect
			100	>320	>320	No Effect
			20	>320	>320	No Effect
			10	>320	-	No Effect
			7	-	>320	No Effect
A.O.[1]	281143	27312	400	>320	-	No Effect
			100	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Biotronik[1]	IDP-44	55038	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Biotronik[1]	IDP-44	61034	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Biotronik[1]	IDP-44	61035	400	>320	>320	No Effect
			200	>320	-	No Effect
			100	>320	>320	No Effect
			40	>320	>320	No Effect
			20	>320	>320	No Effect
			10	>320	-	No Effect
			7	-	>320	No Effect

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Biotronik[1]	IDP-44	61443	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Cordis Atricor[2]	133C6	2210	400	88	-	Reverted
			200	102	-	Reverted
			100	102	-	Reverted
			40	116	-	Reverted
			20	204	-	Reverted
			10	204	-	Reverted
Cordis Atricor[2]	133C7	2352	400	102	-	Erratic Output
			400	129	>320	Tracking
			200	43	-	Erratic Output
			100	43	141	Erratic Output
			100	248	>320	Tracking
			40	43	-	Erratic Output
			40	52	-	Tracking
			20	43	-	Erratic Output
			20	52	141	Tracking
			7	-	141	Tracking
Cordis Atricor[2]	133C7	2958	400	70	-	Erratic Output
			400	102	-	Reverted
			400	129	-	Erratic Output
			200	70	-	Erratic Output
			200	102	-	Reverted
			200	178	-	Erratic Output
			100	70	-	Erratic Output
			40	70	-	Erratic Output
			40	204	-	Reverted
			10	70	-	Reverted
			10	266	-	Erratic Output

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Cordis Omni Atricor[2]	164A	118	400	204	-	Reverted
			400	229	-	No Effect
			200	178	-	Reverted
			200	204	-	No Effect
			100	178	-	Reverted
			100	204	-	No Effect
			40	158	-	Reverted
			20	158	-	Reverted
			10	158	-	Reverted
Cordis Omni Atricor[2]	164A	284	400	178	-	Reverted
			200	141	-	Erratic Output
			200	158	-	Reverted
			100	141	-	Erratic Output
			100	158	-	Reverted
			40	141	-	Reverted
			20	141	-	Reverted
			10	141	-	Reverted
Cordis Omni Atricor[2]	164A	286	400	141	-	Erratic Output
			400	158	-	Reverted
			400	-	>320	No Effect
			200	129	-	Reverted
			100	129	-	Reverted
			100	-	>320	No Effect
			40	129	-	Reverted
			40	-	>320	No Effect
			20	129	320	Erratic Output
			20	116	-	Reverted
			10	116	-	Erratic Output
			10	141	-	Reverted
			7	-	320	Reverted
Cordis Stanicor[2]	143E7	11575	400	40	-	Reverted

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Cordis Stanicor[1]			400	-	>320	No Effect
			200	36	-	Reverted
			100	36	-	No Output
			100	40	302	Reverted
			40	40	-	Reverted
			20	40	-	Reverted
			20	-	302	Erratic Output
			10	40	-	No Output
			10	229	-	Reverted
			7	-	302	No Output
Cordis Omni Stanicor[2]	162C	342	400	>320	-	No Effect
			200	>320	-	No Effect
			100	320	-	Reverted
			40	>320	-	No Effect
			20	302	-	No Output
			20	320	-	No Effect
			10	320	-	No Output
Cordis Omni Stanicor[2]	162C	4246	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Cordis Omni Stanicor[2]	162C	5296	400	>320	>320	No Effect
			200	302	-	Erratic Output
			200	320	-	No Effect
			100	266	-	Erratic Output
			100	-	>320	No Effect
			40	248	-	No Output
			20	248	320	Erratic Output
			10	229	-	Erratic Output
			7	-	302	No Output
			7	-	320	Erratic Output

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
General Electric [1]	A2072D	888012	400	102	248	Reverted
			400	60	-	Erratic Output
			100	-	229	Reverted
			20	-	204	Erratic Output
			7	-	320	Erratic Output
General Electric [1]	A2072D	891930	400	102	64	Erratic Output
			400	320	204	Erratic Output
			200	159	-	Reverted
			100	102	-	Erratic Output
			100	248	-	Erratic Output
			40	102	-	Reverted
			20	102	-	Erratic Output
			10	116	-	Reverted
			7	116	-	Erratic Output
General Electric [3]	A2075A	937015	400	204	-	Erratic Output
			200	204	-	Erratic Output
			100	204	-	Erratic Output
			40	204	-	Erratic Output
			20	204	-	Erratic Output
			10	320	-	Erratic Output
			7	320	-	Erratic Output
General Electric [3]	A2075A	937147	400	102	-	Erratic Output
			400	-	>320	No Effect
			200	102	-	Erratic Output
			100	102	-	Erratic Output
			100	-	>320	No Effect
			40	204	-	Erratic Output
			20	204	-	Erratic Output
			20	-	>320	No Effect
			10	204	-	Erratic Output
			7	-	>320	No Effect

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medcor [2]	3-70A	2015	400	77	102	Erratic Output
			400	-	129	Reverted
			200	77	-	Reverted
			100	77	129	Reverted
			100	5	102	Erratic Output
			40	64	-	Erratic Output
			40	70	-	Reverted
			20	77	116	Reverted
			20	-	204	Erratic Output
			10	77	-	Reverted
			7	72	116	Reverted
Medcor [2]	3-70A	3753	400	60	-	Erratic Output
			200	57	-	Erratic Output
			200	60	-	Reverted
			100	60	-	Reverted
			100	266	-	Erratic Output
			40	60	-	Reverted
			20	60	-	Reverted
			10	60	-	Reverted
			7	60	-	Reverted
Medcor [2]	3-70A	3754	400	102	-	Reverted
			200	102	-	Reverted
			100	102	-	Reverted
			40	102	-	Reverted
			20	102	-	Reverted
			10	102	-	Reverted
			7	102	-	Reverted
Medtronic [2]	5842	03851KK	400	43	-	Reverted
			400	158	-	No Output
			200	43	-	Reverted
			200	158	-	No Output
			100	43	-	Erratic Output
			100	51	-	Reverted
			100	178	-	No Output
			40	43	-	Erratic Output
			40	52	-	Reverted
			20	43	-	Erratic Output

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5842	03851KK	20	47	-	Reverted
			20	52	-	No Output
			10	47	-	Erratic Output
			10	52	-	No Output
Medtronic[2]	5842	16669KK	400	88	-	Reverted
			400	204	-	No Output
			200	102	-	Reverted
			200	229	-	No Output
			100	102	-	Reverted
			100	229	-	No Output
			40	102	-	Reverted
			40	229	-	No Output
			20	102	-	No Output
			10	88	-	No Output
Medtronic[2]	5842	2M00520	400	40	-	Reverted
			200	43	-	Reverted
			100	36	-	Reverted
			40	40	-	Reverted
			20	40	-	No Output
			10	40	-	No Output
Medtronic[2]	5842	2M00522	400	52	-	Reverted
			400	320	-	No Effect
			200	52	-	Reverted
			100	52	-	Erratic Output
			100	39	-	Reverted
			40	52	-	Reverted
			40	229	-	No Output
			20	57	-	No Output
			10	52	-	No Output
Medtronic[2]	5842	2M00815	400	43	-	Reverted
			400	248	-	No Output
			200	43	-	Reverted
			200	248	-	No Output
			100	43	-	Reverted
			100	266	-	No Output
			40	43	-	Reverted

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5842	2M00815	40	266	-	Erratic Output
			40	302	-	No Output
			20	43	-	Erratic Output
			20	47	-	No Output
			10	43	-	Erratic Output
			10	38	-	No Output
Medtronic[2]	5842	2M00981	400	77	-	Reverted
			200	77	-	Reverted
			100	71	-	Erratic Output
			100	77	-	Reverted
			40	71	-	Reverted
			40	229	-	No Output
			20	71	-	Erratic Output
			20	77	-	No Output
			10	71	-	Erratic Output
			10	77	-	No Output
Medtronic[2]	5842	2M02202	400	36	-	No Output
			400	40	-	Reverted
			200	40	-	Reverted
			100	36	-	Reverted
			40	36	-	No Output
			20	36	-	No Output
			10	36	-	No Output
Medtronic[2]	5842	3M00123	400	52	-	No Output
			400	58	-	Reverted
			200	52	-	Reverted
			100	52	-	Reverted
			40	52	-	No Output
			40	77	-	Reverted
			20	52	-	No Output
			10	52	-	No Output
Medtronic[2]	5842	3M00154	400	52	-	Reverted
			200	52	-	Reverted
			100	52	-	Reverted
			40	52	-	No Output

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5842	3M00154	40	64	-	Reverted
			20	52	-	No Output
			10	52	-	No Output
Medtronic[2]	5842	3M00158	400	33	-	Reverted
			400	-	>320	No Effect
			200	33	-	Reverted
			100	33	-	Reverted
			100	-	>320	No Effect
			40	33	-	Reverted
			40	36	-	No Output
			40	43	-	Reverted
			40	129	-	No Output
			20	33	-	Reverted
			20	36	-	No Output
			20	-	>320	No Effect
			10	33	-	Reverted
			10	36	-	No Output
Medtronic[2]	5942	1K19384	400	204	-	Reverted
			200	229	-	Reverted
			100	229	-	Reverted
			40	229	-	Reverted
			20	229	-	Reverted
			20	248	-	No Output
			10	229	-	Reverted
			10	248	-	No Output
Medtronic[2]	5942	1K33732	400	158	-	Reverted
			200	158	-	Reverted
			100	141	-	Reverted
			40	141	-	Reverted
			20	141	-	Reverted
			20	158	-	No Output
			10	141	-	Erratic Output
			10	158	-	No Output
Medtronic[2]	5942	1K39359	400	320	-	Reverted
			200	302	-	Reverted
			100	282	-	Reverted

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5942	1K39359	40	282	-	Erratic Output
			40	302	-	Reverted
			20	302	-	Reverted
			20	320	-	No Output
			10	320	-	No Output
Medtronic[2]	5942	2K18157	400	158	-	Reverted
			200	158	-	Reverted
			100	158	-	Erratic Output
			100	178	-	Reverted
			40	158	-	No Output
			20	158	-	No Output
			10	158	-	No Output
Medtronic[2]	5942	3K04222	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Medtronic[2]	5942	3K04597	400	88	-	Erratic Output
			400	-	>320	No Effect
			200	88	-	Reverted
			100	88	-	Reverted
			100	-	>320	No Effect
			40	88	-	Reverted
			40	102	-	No Output
			40	141	-	Reverted
			40	229	-	No Output
			20	88	-	Reverted
			20	102	-	No Output
			20	-	>320	No Effect
			10	88	-	Reverted
			10	102	-	No Output
Medtronic[2]	5942	3K18607	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect

(Continued)

TABLE VI (Continued)

Pacemaker Identification			Threshold Level			
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5942	3K18607	40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Medtronic[2]	5942	3K20660	400	141	-	Reverted
			200	141	-	Reverted
			100	141	-	Erratic Output
			40	158	-	No Output
			40	204	-	Reverted
			20	158	-	No Output
			10	158	-	No Output
Medtronic[2]	5942	3K29624	400	282	-	Reverted
			200	282	-	Reverted
			100	302	-	Reverted
			40	302	-	No Output
			20	282	-	Erratic Output
			20	302	-	No Output
			10	282	-	No Output
Medtronic[1]	5943	1L1282N	400	60	-	Erratic Output
			400	64	-	Reverted
			-	-	>320	No Effect
			200	88	-	Reverted
			100	-	>320	No Effect
			100	88	-	Reverted
			40	88	-	Reverted
			20	88	-	Reverted
			20	-	>320	No Effect
			20	102	-	No Output
			10	102	-	Reverted
			10	116	-	No Output
			7	-	>320	No Effect
Medtronic[2]	5944	3G20824	400	266	-	Erratic Output
			200	266	-	Erratic Output
			200	282	-	Reverted
			100	266	-	Erratic Output
			100	282	-	Reverted
			40	266	-	Erratic Output

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[2]	5944	3G20824	40	282	-	Reverted
			20	266	-	Reverted
			10	266	-	Reverted
			10	282	-	Erratic Output
Medtronic[2]	5944	3G20877	400	178	-	Reverted
			400	-	>320	No Effect
			200	178	-	Erratic Output
			200	229	-	Reverted
			100	-	>320	No Effect
			100	178	-	Reverted
			40	178	-	Reverted
			20	178	-	Reverted
			20	-	>320	No Effect
			10	178	-	No Output
Medtronic[2]	5944	3G20881	400	266	-	Reverted
			200	302	-	Erratic Output
			200	320	-	Reverted
			100	302	-	Reverted
			40	302	-	Reverted
			20	302	-	Reverted
			10	302	-	Reverted
			10	320	-	No Output
Medtronic[1]	5950	3XX2022	400	>320	>320	No Effect
			200	>320	-	No Effect
			100	>320	>320	No Effect
			40	>320	-	No Effect
			20	>320	>320	No Effect
			10	>320	-	No Effect
			7	-	>320	No Effect
Medtronic[1]	5951	3XX2025	400	>320	>320	No Effect
			200	>320	-	No Effect
			100	>320	>320	No Effect
			40	>320	-	No Effect
			20	>320	>320	No Effect
			10	>320	-	No Effect
			7	-	>320	No Effect

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Medtronic[1]	9000	3R00001	400	60	-	Reverted
			400	-	>320	No Effect
			200	57	-	Reverted
			100	57	-	Reverted
			100	-	>320	No Effect
			40	52	-	Erratic Output
			40	57	-	Reverted
			20	57	-	No Output
			20	-	>320	No Effect
			10	57	-	No Output
Medtronic[1]	9000	3R00003	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Medtronic[1]	9000	3R00004	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Pacesetter[2]	BD-101	1196KC	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Pacesetter[2]	BD-101	1395ND	400	>320	>320	No Effect
			200	>320	-	No Effect
			100	>320	>320	No Effect
			40	>320	-	No Effect
			20	>320	>320	No Effect
			10	>320	-	No Effect
			7	-	>320	No Effect
Pacesetter[2]	BD-101	1404ND	400	>320	-	No Effect

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Pacesetter[2]	BD-101	1404ND	200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Star-Edwards[3]	8114	4399	400	77	266	Reverted
			400	-	248	No Output
			200	102	-	Reverted
			100	60	204	Reverted
			40	60	-	Reverted
			20	102	-	Reverted
			20	-	204	No Output
			20	-	>320	No Effect
			10	60	-	No Output
			10	56	-	No Effect
			7	-	204	No Output
Starr-Edwards[2]	8116	ELX15514	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Starr-Edwards[2]	8116	ELX15518	400	>320	>320	No Effect
			200	>320	-	No Effect
			100	>320	>320	No Effect
			40	>320	-	No Effect
			20	>320	>320	No Effect
			10	>320	-	No Effect
			7	-	>320	No Effect
Starr-Edwards[2]	8116	ELX15520	400	>320	-	No Effect

(Continued)

TABLE VI (Continued)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Starr-Edwards[2]	8116	ELX15520	200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Stimtech.[1]	3821	CA88	400	178	-	Reverted
			200	141	-	No Output
			200	178	-	Erratic Output
			100	158	-	Erratic Output
			40	178	-	No Output
			40	204	-	Reverted
			40	282	-	No Output
			40	302	-	Reverted
			20	158	-	No Output
			20	302	-	Reverted
			10	178	-	No Output
Stimtech[1]	3821	H3B030	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	>320	-	No Effect
			20	>320	-	No Effect
			10	>320	-	No Effect
Stimtech[1]	3821	J3B015	400	320	-	No Output
			400	-	>320	No Effect
			200	302	-	No Output
			200	320	-	Erratic Output
			100	302	-	No Output
			100	320	-	Reverted
			100	-	>320	No Effect
			40	302	-	No Output
			20	302	-	No Output
			20	-	>320	No Effect
			10	302	-	No Output
			7	-	>320	No Effect

(Continued)

TABLE VI (Concluded)

Pacemaker Identification				Threshold Level		
Mfg.	Model Number	Serial Number	Pulse Rate (pps)	Open Air (V/m)	Saline (V/m)	Pacemaker Response
Stimtech[1]	3821	J3B016	400	>320	-	No Effect
			200	>320	-	No Effect
			100	>320	-	No Effect
			40	320	-	No Output
			20	320	-	No Output
			10	320	-	No Output
Vitatron[3]	MIP-40-RT	0505	400	102	-	Reverted
			400	204	-	Erratic Output
			200	102	-	Reverted
			100	102	-	Reverted
			40	102	-	Reverted
			40	229	-	Erratic Output
			20	204	-	Erratic Output
			10	204	-	Erratic Output
			7	204	-	Reverted
Vitatron[3]	MIP-40-RT	0507	400	204	-	Tracking
			400	302	-	Erratic Output
			10	204	-	No Effect
			7	>204	-	No Effect
Vitatron[3]	MIP-40-RT	5146	400	102	204	Reverted
			400	204	-	Erratic Output
			200	178	-	Reverted
			200	204	-	Erratic Output
			100	158	-	Reverted
			100	178	-	Erratic Output
			100	-	>320	No Effect
			40	158	-	Reverted
			20	158	320	Reverted
			10	178	-	Reverted
			7	158	-	Reverted
			7	-	>320	No Effect

Notes: 1. Pacemaker positioned such that label was toward antenna.
2. Pacemaker positioned such that label was away from antenna
3. Pacemaker positioned such that ground plate was away from antenna.

4.2.4 3.1 GHz Susceptibility Thresholds As A Function of Pulse Rate, Pulse Width, and Field Intensity

A sample of ten pacemakers was evaluated to more precisely define their electromagnetic characteristics as a function of both pulse rate and width. All evaluations were conducted with the pacemakers mounted in an open air medium. For this series of evaluations, the pacemaker orientation on the Plexiglas® support was changed from that shown in Figure 11 to that shown below in Figure 14. This orientation change was necessary to facilitate pacemaker rotation during the evaluations. Rotation was required in order to subject both sides of the pacemaker to the exposure field. Because of this change in orientation, the susceptibility thresholds presented in Table VI should not be compared to those measured during this series of evaluations. The exposure field was linearly polarized and the susceptibility thresholds are presented in terms of rms levels of field intensity during the time the "RF" pulse was present. Data resulting from these evaluations are presented in Table VII.

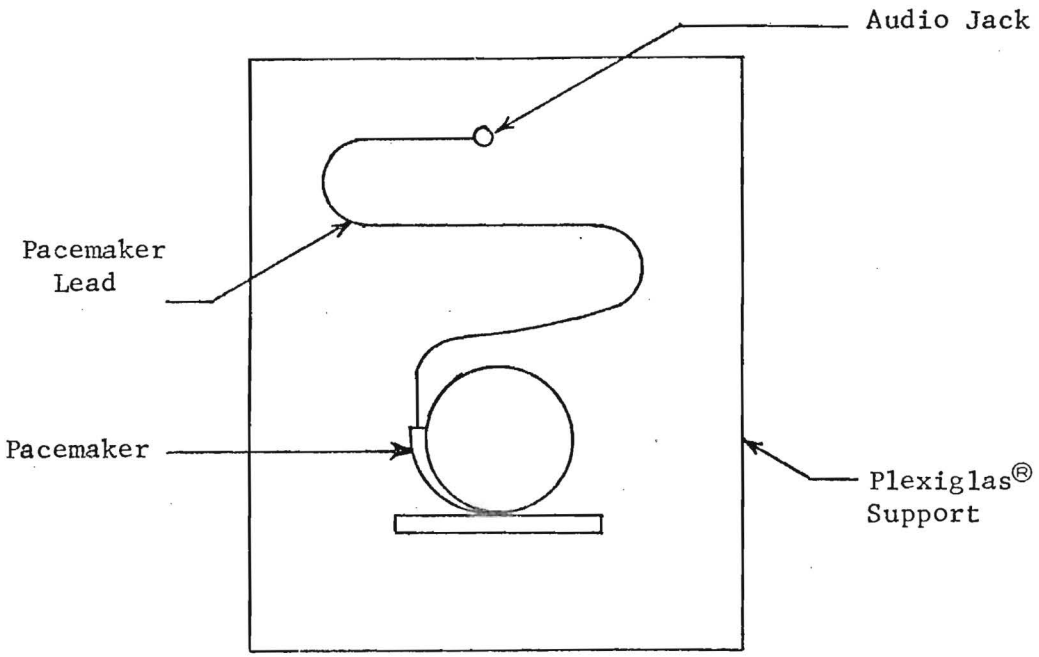

Figure 14. Reorientation of Pacemaker Position.

TABLE VII

PACEMAKER RESPONSE TO A 3.1 GHz PULSED ELECTROMAGNETIC FIELD WITH VARIABLE PULSE RATE AND WIDTH

Pacemaker Identification			Pulse Parameters			
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	Threshold Level (V/m)	Pacemaker Response
A.O.	281143	27560	120	400	>320	No Effect
			10	400	>320	No Effect
			120*	400	>320	No Effect
A.O.	281003	11591	120	400	141	Erratic Output
			120	400	178	Reverted
			120	7	158	No Output
			50	400	177	No Output
			50	7	204	No Output
			20	400	229	No Output
			20	7	248	No Output
			10	400	248	Erratic Output
			10	7	302	No Output
			120*	400	177	Erratic Output
			120*	7	177	No Output
Cordis Omni Atricor	133C7	2352	120	400	36	Reverted
			120	7	33	Reverted
			50	400	36	Erratic Output
			50	7	36	Erratic Output
			20	400	43	Erratic Output
			20	7	43	Reverted
			10	400	57	Erratic Output
			10	7	57	Erratic Output
			120*	400	64	Erratic Output
Cordis Omni Atricor	164A	286	120	400	116	Erratic Output
			120	7	102	Reverted
			50	400	129	Reverted
			50	7	116	Reverted
			20	400	158	Reverted
			20	7	141	Reverted
			10	400	178	Reverted
			10	7	158	Reverted
			120*	7	116	Reverted

(Continued)

TABLE VII (Continued)

Pacemaker Identification			Pulse Parameters			
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	Threshold Level (V/m)	Pacemaker Response
General Electric	A2072D	891930	120	400	77	Erratic Output
			120	7	77	Erratic Output
			50	400	77	Erratic Output
			50	7	116	Erratic Output
			20	400	102	Erratic Output
			20	7	158	Erratic Output
			10	400	102	Erratic Output
			10	7	178	Erratic Output
			120*	400	60	Erratic Output
			120*	7	141	Erratic Output
Medtronic	5842	3M00158	120	400	33	Erratic Output
			120	7	33	Erratic Output
			50	400	47	Reverted
			50	7	47	Erratic Output
			20	400	77	Reverted
			20	7	77	No Output
			10	400	102	Reverted
			10	7	102	Erratic Output
			120*	400	33	No Output
Medtronic	5942	3K04597	120	400	177	Reverted
			120	7	158	No Output
			50	400	248	Reverted
			50	7	229	No Output
			20	400	>320	No Effect
			20	7	>320	No Effect
			10	400	>320	No Effect
			10	7	>320	No Effect
			120*	400	128	Reverted
Medtronic	5943	1L1282N	120	400	77	Reverted
			120	7	72	Erratic Output
			50	400	102	Reverted

(Continued)

TABLE VII (Concluded)

Pacemaker Identification			Pulse Parameters		Threshold Level	Pacemaker Response
Mfg.	Model Number	Serial Number	Width (μsec)	Rate (pps)	(V/m)	
Medtronic	5943	1L1282N	50	7	116	Reverted
			20	400	141	Reverted
			20	7	158	Erratic Output
			10	400	178	Reverted
			10	7	204	Reverted
			120*	400	88	Erratic Output
Medtronic	5944	3G20877	120	400	129	Reverted
			120	7	129	No Output
			50	400	178	Reverted
			50	7	178	Reverted
			50	7	204	No Output
			20	400	248	Reverted
			20	7	266	Erratic Output
			10	400	320	Erratic Output
			10	7	>320	No Effect
			120*	400	229	Reverted
Medtronic	9000	3R00001	120	400	88	Reverted
			120	7	77	No Output
			50	400	116	Reverted
			50	7	116	No Output
			20	400	178	Reverted
			20	7	178	No Output
			10	400	229	Reverted
			10	7	229	No Output
			120*	400	229	Reverted

*Normal orientation inverted.

5. CONCLUSIONS

The major conclusions resulting from these evaluations are summarized as follows:

(a) During these evaluations, 72 different pacemakers representing ten manufacturers and 23 models were subjected to pulsed electromagnetic environments at frequencies of 450 MHz and 3.1 GHz. These pacemakers included models into which design changes had been incorporated and new designs only recently available commercially. At both test frequencies, the pacemakers were generally less susceptible than their predecessors of approximately two years ago. Recently introduced pacemaker designs tended to be considerably less susceptible than those of existing models into which circuit modifications had been incorporated.

(b) At 450 MHz, the average value of the ratios of susceptibility thresholds in saline solution relative to open air is 3.015. The average value of these susceptibility threshold ratios at 3.1 GHz is 2.505. These data indicate that addition of the 0.03 Molar saline solution to the test configuration decreases pacemaker susceptibility by an average of 9.6 dB and 8.0 dB, respectively, at the 450 MHz and 3.1 GHz test frequencies. The 9.6 dB at 450 MHz was considerably higher than anticipated based on results of earlier evaluations. The reason for this was not investigated at the time these evaluations were conducted. It is noted, however, that comparison of these data with data from previous evaluations is difficult because different test configurations were used.

(c) An overview of pacemaker susceptibility as a function of pulse repetition is provided in Figures 15 and 16. From these figures it was concluded that, if electromagnetic interferance occurred at low pulse repetition rates, the susceptibility mode was highly likely to be inhibition of the pacemaker's output. Conversely, interference at high pulse repetition rates was highly likely to cause rate reversion as the mode of susceptibility. Erratic output as a susceptibility mode did not exhibit any distinguishable dependency on pulse repetition rate.

(d) Figures 17 and 18 provide a view of pacemaker susceptibility at 450 MHz as a function of pulse width. From Figure 17 where the pulse repetition rate was maintained at 2 pulses per second, it is concluded that the "No Output" susceptibility mode occurred more often as the pulse width increased. This mode was also significantly more predominant as a susceptibility mode. For the 50 pulse per second repetition rate in Figure 18, the "No Output" susceptibility mode did not predominate; instead, the pulse width dependency occurred for the "Reverted Output" mode. Erratic pacemaker output did not appear to be sensitive to pulse width variations at either of the two pulse repetition rates.

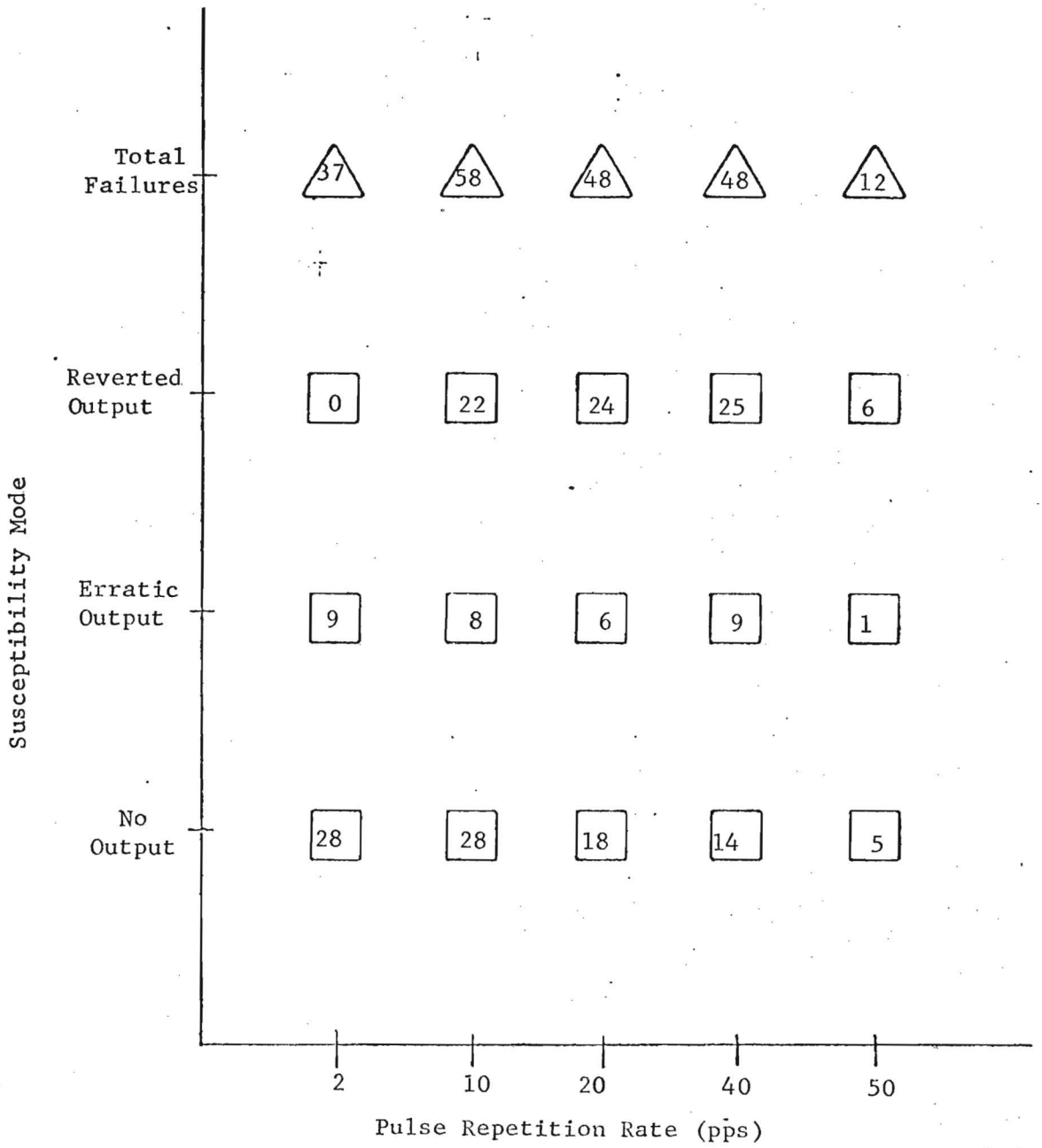

Figure 15. Pacemaker Susceptibility As a Function of Pulse Rate at 450 MHz (Pulse Width = 1.2 Milliseconds).

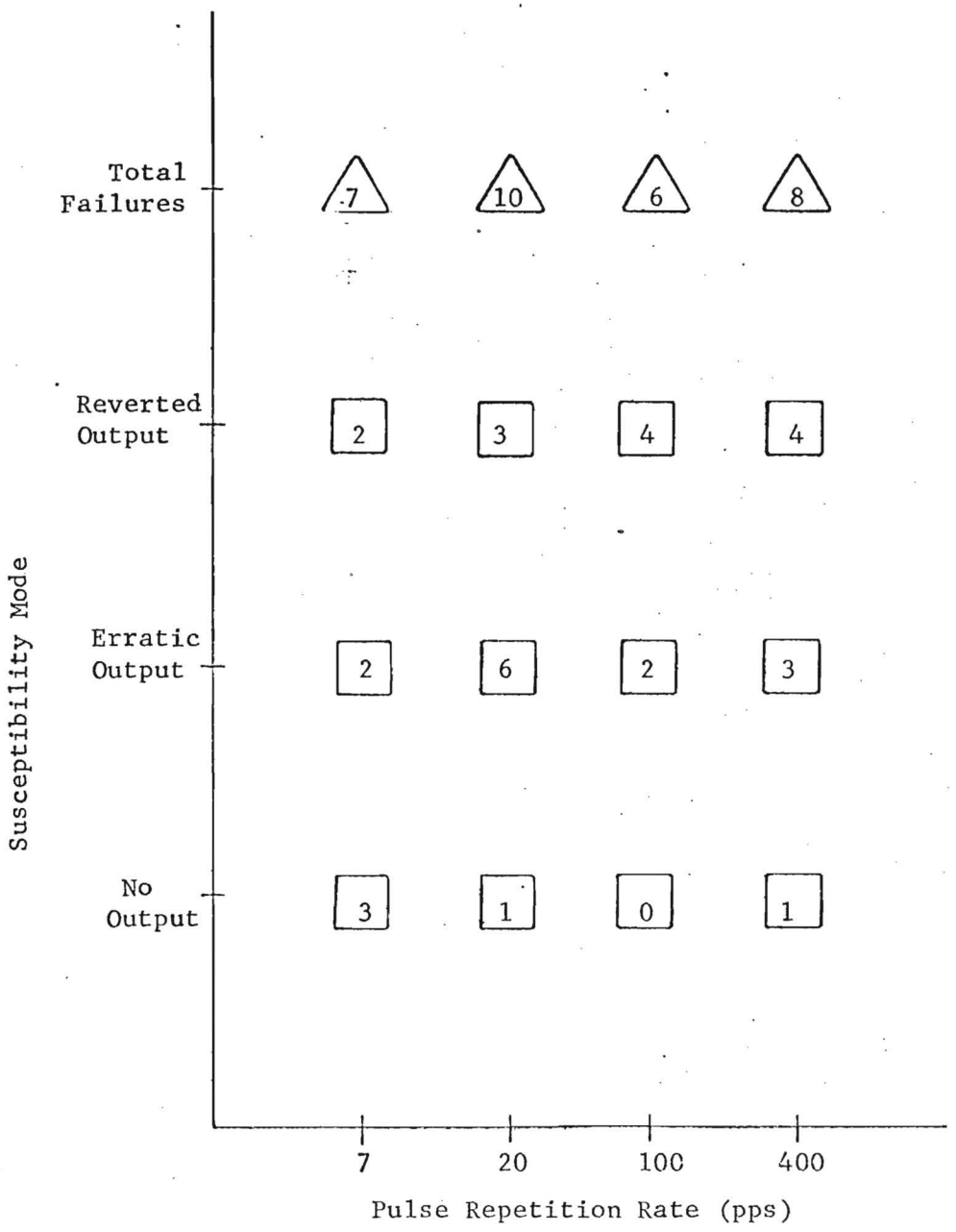

Figure 16. Pacemaker Susceptibility As a Function of Pulse Rate at 3.1 GHz (Pulse Width = 120 Microseconds).

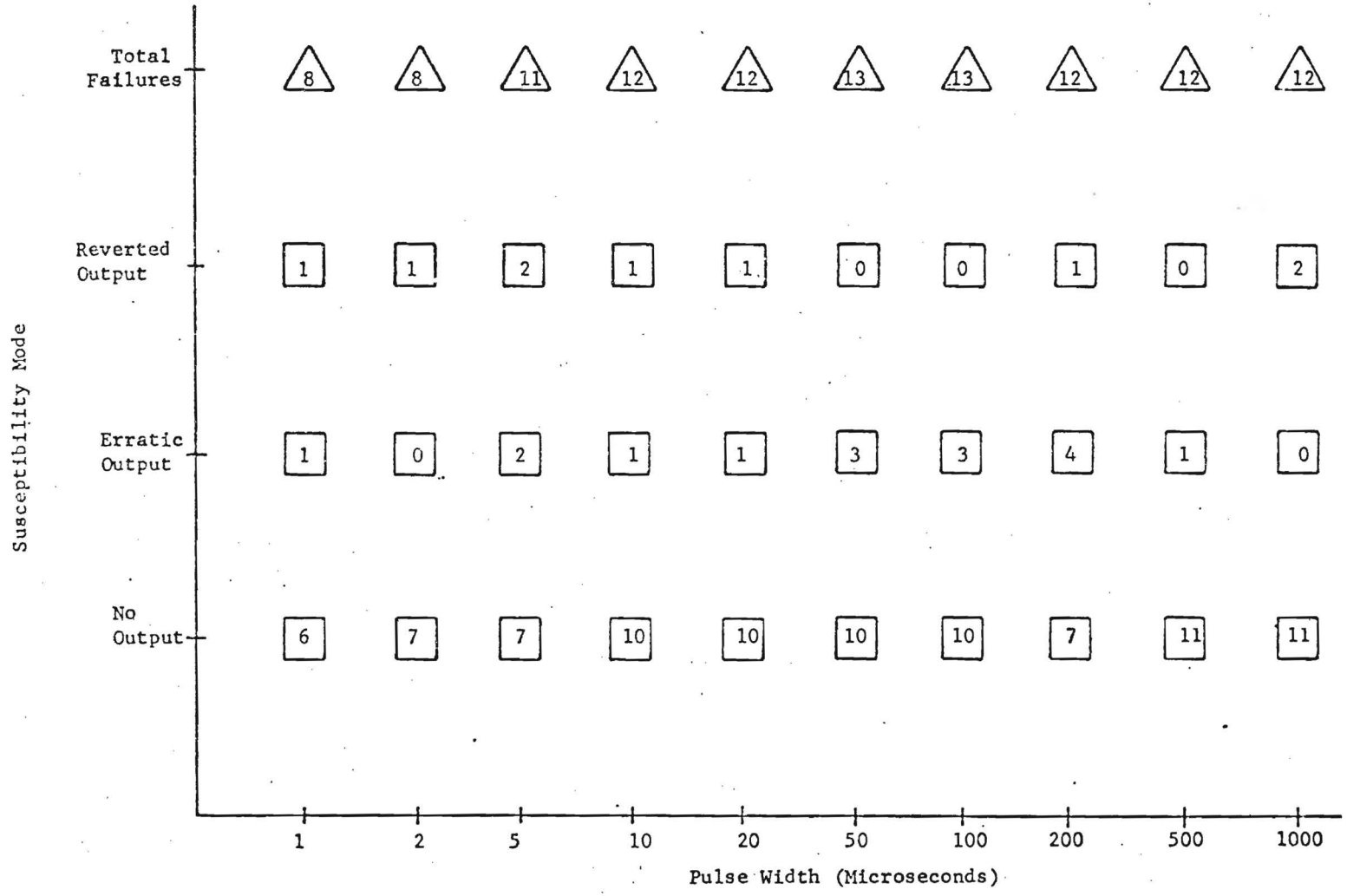

Figure 17. Pacemaker Susceptibility As a Function of Pulse Width at 450 MHz (Pulse Rate = 2 pps).

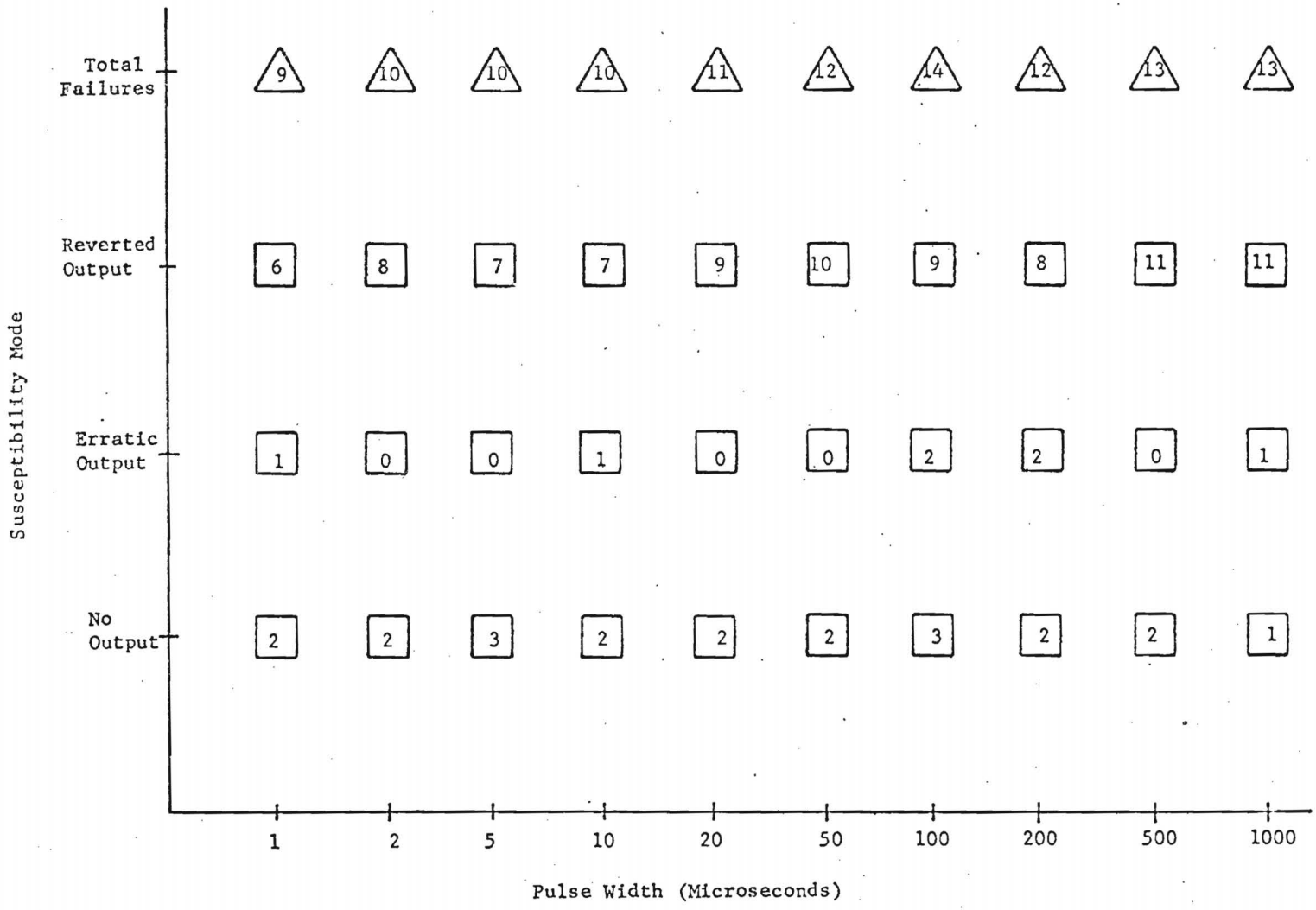

Figure 18. Pacemaker Susceptibility As a Function of Pulse Width at 450 MHz (Pulse Rate = 50 pps).

(e) The data in Figures 19 and 20 show the influence of pulse width on pacemaker susceptibility at 3.1 GHz. As was the case at 450 MHz, conclusions based on these data included the fact that, at the 7 pulse per second repetition rate, the predominate susceptibility mode was pacemaker pulse inhibition. The reverse of this situation existed at the 400 pulse per second repetition rate.

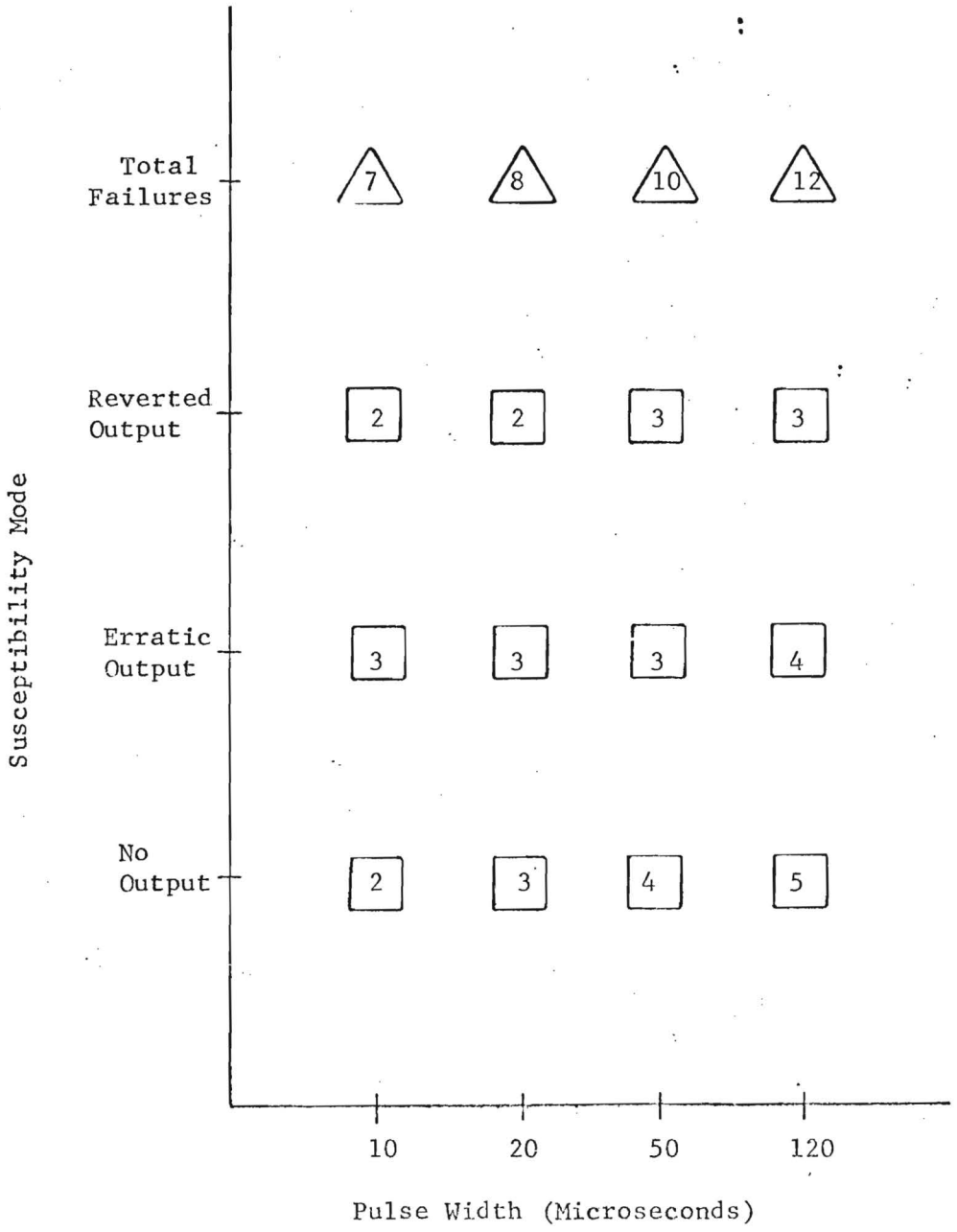

Figure 19. Pacemaker Susceptibility As a Function of Pulse Width at 3.1 GHz (Pulse Rate = 7 pps).

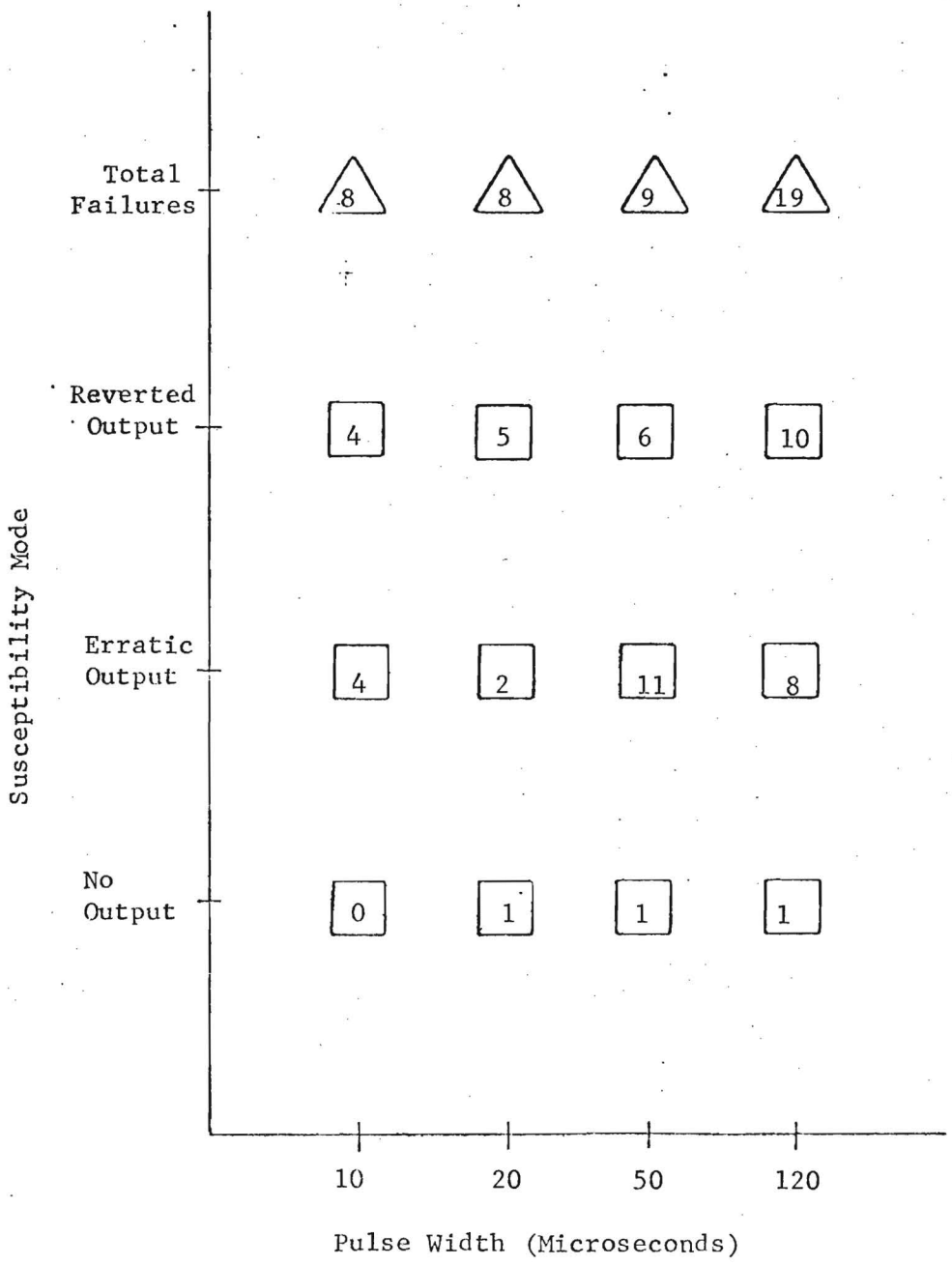

Figure 20. Pacemaker Susceptibility As a Function of Pulse Width at 3.1 GHz (Pulse Rate = 400 pps).

6. REFERENCES

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